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In the Supreme Court of the United States

APOTEX, INC.,

Petitioner,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Under the Hatch-Waxman Act, 21 U.S.C. §§ 301 *et seq.*, the first generic drug manufacturer to challenge a dubious patent claimed for a brand-name drug may be rewarded with a 180-day period within which only that company will be permitted to market a generic drug. As a practical matter, winning exclusivity for even a single generic can be worth hundreds of millions of dollars. In 2003, Congress responded to abuses of this provision by prescribing a series of "forfeiture events" that cause the generic manufacturer to lose such marketing exclusivity. Among other things, forfeiture is triggered when the challenged patent "is withdrawn by" the brand-name manufacturer or has "expired."

The D.C. Circuit held that, notwithstanding the absence of a textual limitation, forfeiture could not be triggered by "unilateral" action by the brand-name manufacturer. Relying on a prior decision interpreting the *pre*-2003 statutory scheme (and rejecting FDA's long-held position), the court of appeals concluded that such a limitation is required by the statute's "intended incentive structure." The question presented is:

> Whether a generic drug manufacturer may forfeit marketing exclusivity under 21 U.S.C. § 355(j)(5)(D) based on "unilateral" action by the holder of the challenged patent.

PARTIES TO THE PROCEEDING

The petitioner, plaintiff-appellant below, is Apotex, Inc.

The respondents, defendants-appellees below, are Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services; Margaret Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs; United States Food and Drug Administration; and United States Department of Health and Human Services, as well as Teva Pharmaceuticals, USA, Inc., intervenor-defendant-appellee below. Roxane Laboratories, Inc. was also a plaintiff-appellant below and is therefore a respondent under this Court's Rule 12.6.

RULE 29.6 STATEMENT

The ultimate parent of petitioner Apotex, Inc. is Sherfam Inc., which is not publicly traded. No publicly traded company owns 10% or more of the shares of petitioner or of any of its parent corporations.

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JURISDICTION

The judgment of the court of appeals was entered on July 6, 2010. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant statutory provisions are set forth at App., *infra*, 107a-114a.

STATEMENT

This case involves the statutory scheme governing the generic drug industry. In 1984, Congress passed landmark legislation designed to foster the development of generic drugs as lower-cost alternatives to their brand-name equivalents. That effort was highly successful, giving rise to the multi-billion-dollar generic drug industry that benefits virtually every American today.

In 2003, with the generic industry firmly established, Congress amended the statute to facilitate

increased competition *among* generic manufacturers and thereby to drive drug prices down further. The amendments modified one of the statutory provisions designed to encourage generic manufacturers to challenge inappropriate patent claims made by a brand-name manufacturer hoping to stave off generic competition. That provision awarded the first generic manufacturer to bring such a challenge a period of market exclusivity during which only its product could compete with the brand-name product. Recognizing the significant costs that such an anti-competitive reward imposed on consumers, and questioning the continued need for such incentives, Congress amended the statute to enumerate no fewer than six circumstances in which a generic manufacturer would forfeit the period of market exclusivity.

In the decision that led to the decision below, the D.C. Circuit concluded that enforcing the plain language of those amendments would disrupt what the court of appeals believed to be the statute's "intended incentive structure." App., *infra*, 60a. Relying almost entirely on a prior circuit decision interpreting the *pre*-2003 version of the statute, the D.C. Circuit rejected FDA's contrary reading of the statute and held that a generic manufacturer's market exclusivity cannot be forfeited as a result of "unilateral" action by the brand-name manufacturer. App., *infra*, 62a-63a. That erroneous and textually ungrounded conclusion—besides rejecting the views of the expert agency—mangled a critical component of an indisputably vital federal statute, resulting in the imposition of literally billions of dollars in costs to health-care consumers that Congress never intended. Indeed, the government has rightly acknowledged

that this question is "exceptionally important." See *infra* p. 14.

A. The Statutory Framework

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the "Hatch-Waxman Act," regulates the FDA approval process for brand-name and generic drugs. A primary objective of the Act is "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. The Act established a framework designed to promote generic competition and speed the FDA approval process for generic drugs. See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (the Hatch-Waxman Act allows drugs to be "marketed more cheaply and quickly"). In pursuing that larger goal, Congress balanced two sometimes competing considerations: (1) rewarding generic drug companies for challenging brand-name manufacturers' use of dubious patent claims to ward off generic competition; and (2) encouraging robust and rapid competition *among* generic drug companies to achieve the lowest possible price for consumers. In 2003, Congress amended the Act to recalibrate the balancing point between those objectives; this case turns on whether, in doing so, Congress should be taken at its word.

1. When seeking to introduce a new drug into the market, brand-name drug makers must submit a new drug application (NDA) to the FDA. The NDA must include detailed pharmacological and clinical information demonstrating that the drug proved safe and effective in a rigorous testing regimen, including human trials. 21 U.S.C. § 355(a),(b); see *Merck*

KGaA v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005). The NDA must also identify the number and expiration date for all patents that cover the new drug—*i.e.*, those patents that the manufacturer believes protect the new brand-name drug. 21 U.S.C. § 355(b)(1). Once an NDA is approved, FDA publishes that patent information in the "Approved Drug Products with Therapeutic Evaluations" book, 21 C.F.R. § 314.53(e), commonly known as the "Orange Book." So long as the patents listed in the Orange Book are valid and in force—and a would-be competitor cannot design around them—the brand-name manufacturer generally enjoys monopoly power in selling the new drug.

While recognizing that monopolistic rewards are sometimes necessary to encourage the development of new drugs, Congress also wanted to foster prompt competition by and among generic drug makers. Accordingly, the Hatch-Waxman Act significantly streamlined the generic drug approval process by authorizing abbreviated new drug applications (ANDAs) for generic drugs. See *Merck*, 545 U.S. at 196 n.1; *Eli Lilly*, 496 U.S. at 676. If the ANDA establishes that the generic drug is bioequivalent to an approved brand-name drug, the ANDA can rely on the same clinical safety and efficacy data used to support the brand-name drug NDA, which eliminates costly and time-consuming duplication of clinical studies. See *Eli Lilly*, 496 U.S. at 676; *Merck*, 545 U.S. at 196 n.1 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv), 355(j)(8)(B)).

ANDA applicants are required to review the patent information published in the Orange Book for the brand-name drug that the ANDA references. For

each listed patent, ANDA applicants must then certify: (I) that "such patent information has not been filed"; (II) "that such patent has expired"; (III) "the date on which such patent will expire"; or (IV) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii). These certifications are known by their respective paragraph numbers; this case principally concerns "paragraph IV" certifications.

2. If an ANDA contains a paragraph IV certification, the applicant must provide the brand-name drug maker with written notice setting forth the basis for that challenge. 21 U.S.C. § 355(j)(2)(B). The filing of a paragraph IV certification constitutes an act of patent infringement, 35 U.S.C. § 271(e)(2)(A), and the brand-name drug maker can therefore sue any such ANDA applicant to defend the validity or applicability of the disputed patent. 21 U.S.C. § 355(j)(5)(B)(iii). If the brand-name drug maker files suit within 45 days, approval of the ANDA is automatically stayed for 30 months to allow the completion of the litigation. *Ibid.*

Paragraph IV certifications are the primary means by which generic drug makers challenge potentially improper patents associated with brand-name drugs. The removal of improper patents from the Orange Book can result in earlier generic competition, ultimately reducing costs to consumers. See *Teva Pharmaceuticals, USA, Inc.* v. *Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA

holders in order to bring generic drugs to market earlier.").[1]

3. The Hatch-Waxman Act sought to encourage generic drug manufacturers to challenge questionable brand-name patents by rewarding the first ANDA applicant to file a paragraph IV certification for a given patent and drug (the "first applicant") with a 180-day period of generic market exclusivity. During that period, approval of any other ANDA for that same drug is delayed, and the first applicant alone is permitted to sell its generic version of the brand-name drug. Exclusivity is tremendously valuable; it allows the first applicant to offer a competing product for a brand-name drug that typically has a significant established market. Better still, because other generics cannot yet enter the market, the first applicant competes only with the brand-name manufacturer, allowing the generic to charge near-monopoly prices while still acquiring significant market share.[2]

That delay in full generic competition imposes substantial costs on consumers. See FTC, Prepared Statement Before the Senate Judiciary Committee (June 17, 2003) ("FTC Statement"), *available at* http://www.ftc.gov/os/2003/06/030617pharmtestimony

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[1] Suppose, for example, that a brand-name drug lists patents A, B, and C in the Orange Book. Suppose further that patents A and B squarely cover the brand-name drug but are set to expire in short order, whereas patent C is of dubious applicability or validity but has a more distant expiration date. A brand-name drug maker might list patent C in the Orange Book in hopes of delaying competition from generics.

[2] As explained in greater detail below (*infra* pp. 21-22), the first applicant's market advantages often linger well beyond expiration of the formal exclusivity period.

.htm) ("After the 180 days, subject to regulatory approvals, other generic companies can enter the market * * *. *Empirical research demonstrates that as additional generic competitors enter the market, generic prices decrease to lower levels, thus [benefiting] consumers.*") (emphasis added). The generic manufacturer with exclusivity can charge a much higher price as the lone competitor to the brand-name drug than it can once other generic manufacturers have entered the market.

4. Congress came to understand the costs that exclusivity, or duopoly, imposes on consumers. Experience under the original Hatch-Waxman Act showed that "brand and generic companies * * * abused [the 180-day] exclusivity period—both through collusive agreements and use of other tactics that allow the [exclusivity] provision to act as a bottleneck to generic competition." 149 Cong. Rec. S15,746 (daily ed. Nov. 24, 2003) (Sen. Schumer). In response, Congress in 2003 passed the Medicare Prescription Drug, Improvement, and Modernization Act (the "MMA"), which revised the 180-day generic exclusivity provisions to limit more tightly eligibility for exclusivity. 149 Cong. Rec. S15,884 (daily ed. Nov. 25, 2003) (Sen. Kennedy) (explaining that the MMA "restructure[s] how the 180-day generic exclusivity provisions work" by limiting eligibility for exclusivity); *id.* at S15,746 (Sen. Schumer) (the MMA recalibrates the balance between providing an incentive for generic applicants to challenge patents, and limiting the 180-day exclusivity award to "ensure[] that consumers have access to a low-cost generic as soon as possible").

The MMA enumerated six specific "forfeiture events" that will cause an otherwise eligible first applicant to lose its eligibility for exclusivity. 21 U.S.C. § 355(j)(5)(D). Two of those forfeiture events—"Failure to market" following the brand-name manufacturer's delisting of the patent from the Orange Book (§ 355(j)(5)(D)(i)(I)) and "Expiration of all patents" claimed by the brand-name manufacturer (§ 355(j)(5)(D)(i)(VI))—are at issue here.

a. *Patent delisting.* Full-scale litigation will not always be necessary to remove a challenged patent from the Orange Book. After a paragraph IV certification is filed, the brand-name manufacturer may ask FDA to "delist" the patent, effectively removing it as a barrier to generic competition. In enacting the MMA, Congress determined that such acquiescence would not result in exclusivity unless the first applicant can promptly bring the generic drug to market.

The relevant provisions of the MMA are densely worded but clear in application: If the patent as to which the first applicant has filed a paragraph IV certification is "withdrawn by the [brand-name manufacturer]," the first applicant forfeits exclusivity unless it brings the generic to market within the *longer* of (1) 75 days of delisting of the challenged patent or (2) the *earlier* of either 30 months from the date of the paragraph IV certification, or 75 days of final approval of the ANDA. 21 U.S.C. § 355 (j)(5)(D)(i)(I). Thus, even first applicants that do not bear the burdens of litigating a disputed patent are rewarded with exclusivity if they are able to move quickly enough in marketing the generic. Conversely, first applicants whose principal accomp-

lishment is winning a race to file an ANDA—but do not rapidly bring a drug to market—are not entitled to reap the massive benefits of exclusivity.

b. *Patent expiration.* The MMA also specified that a first applicant will not enjoy exclusivity if the challenged patent has expired. More particularly, the MMA states that the "180-day exclusivity period * * * shall be forfeited" when "[a]ll of the patents as to which the applicant submitted a [Paragraph IV] certification qualifying it for the 180-day exclusivity period have expired." 21 U.S.C. § 355(j)(5)(D)(i)(VI), (D)(ii). The statute does not limit forfeiture to expiration resulting from a particular cause.

This provision reflects FDA's "longstanding interpretation" of the Hatch-Waxman Act to require that, "once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished." App., *infra*, 19a; see *id.* at 20a ("The forfeiture provision at section 505(j)(5)(D)(i)(VI), enacted in the MMA, thus embodies the familiar principle that 180-day exclusivity does not survive patent expiration."). Numerous courts had upheld FDA's interpretation before the MMA's enactment. See, *e.g.*, *Dr. Reddy's Labs., Inc.* v. *Thompson*, 302 F. Supp. 2d 340, 357 (D.N.J. 2003); *Ranbaxy Labs., Ltd.* v. *Leavitt*, 469 F.3d 120, 126 n.* (D.C. Cir. 2006); *Ranbaxy Labs. Ltd.* v. *FDA*, 307 F. Supp. 2d 15, 19-20 (D.D.C. 2004), aff'd, 96 F. App'x 1 (D.C. Cir. 2004). Thus, the MMA forfeiture provisions codified FDA's conclusion that "permitting the first applicant to retain exclusivity as to an expired patent requires FDA to take an action that is not sanctioned by the words of the statute." App., *infra*, 25a.

B. Proceedings Below

Respondent Teva and petitioner Apotex are generic drug manufacturers and direct competitors. In 2003 and 2004, Teva filed ANDAs seeking FDA approval to market generic versions of two brand-name hypertension drugs—Cozaar and Hyzaar—manufactured by Merck. Both drugs contained the active ingredient losartan. Merck listed three patents in the Orange Book for both losartan drugs. Teva's ANDAs contained paragraph IV certifications for one of those patents: Patent No. 5,608,075 (the "'075 patent").[3] Apotex and several other generic manufacturers subsequently filed their own losartan ANDAs, and each of those ANDAs likewise contained a paragraph IV certification for the '075 patent. Merck elected not to sue any of the ANDA applicants for patent infringement. Merck ultimately requested that FDA delist the '075 patent from the Orange Book, which FDA did in April 2008.

1. *Teva* v. *Sebelius*

In June 2009, before FDA rendered a final decision on Teva's eligibility for exclusivity, Teva filed suit seeking to prevent FDA from enforcing the MMA's delisting forfeiture provision. Teva argued that the "delisting rule," which FDA had applied in agency decisions following enactment of the MMA,[4] was in excess of FDA's statutory authority and that

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[3] In addition to the '075 patent, Merck listed Pat. Nos. 5,138,069 and 5,153,197. Teva and Apotex both submitted paragraph III certifications for the latter two patents, listing the date on which the patents were set to expire.

[4] See FDA Acarbose Decision Letter (May 7, 2008) (FDA Docket No. 2007-N-0445); FDA COSOPT Decision Letter (Oct. 28, 2008) (FDA Docket No. 2008-N-0483).

Teva therefore had not forfeited its right to 180-day exclusivity by virtue of Merck's delisting of the '075 patent.

The district court disagreed and upheld FDA's reading of the statute. App., *infra*, 72a-106a. The patent delisting forfeiture event, the court explained, "is not ambiguous on its face": The text explicitly provides that an ANDA applicant forfeits exclusivity when it fails to market a drug after the relevant "'patent information * * * is withdrawn'" from the Orange Book. *Id.* at 98a-99a (quoting 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC)). The court further held that, even if the MMA forfeiture provision could be "construed * * * to be ambiguous, the Court would be required to defer to the FDA's interpretation" of the statute because "FDA's interpretation of the statute is reasonable." *Id.* at 100a.[5]

The D.C. Circuit reversed. App., *infra*, 31a-71a.[6] The majority did not dispute that the MMA added "a

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[5] The district court denied Apotex's motion to intervene, concluding that Apotex's interests in the suit were too speculative at that time because FDA had not yet given Apotex's ANDA scientific approval. App., *infra*, 103a-105a. The district court permitted Apotex to appear as *amicus curiae*. *Id.* at 105a.

[6] Judge Henderson dissented, concluding that "the issue Teva seeks to litigate * * * will not be ripe unless and until [FDA] issues its final decision either granting or denying Teva's [ANDA]." App., *infra*, 67a. Apotex appealed the district court's denial of its motion to intervene and filed an *amicus* brief in the D.C. Circuit "express[ing] its substantive views of this case." *Id.* at 65a. The panel majority "considered" that brief "no less than if Apotex had formally intervened" in the district court but declined to resolve the intervention question under a "line of precedent in [the D.C. Circuit] declining to assess a would-be intervenor's standing when answering the question wouldn't affect the outcome of the case." *Ibid.*

critical new term to the statute: the 'forfeiture event.'" App., *infra*, 36a. Nor did it dispute that the statute declared that exclusivity "*shall* be forfeited by a first applicant" when it fails to market the generic drug within the specified time after the challenged patent "is withdrawn by the holder" (*i.e.*, the brand-name manufacturer). 21 U.S.C. § 355(j)(5)(D)(i)(I), (D)(ii) (emphasis added). Nevertheless, the panel concluded that FDA's reading of the statute "fails at *Chevron* step one"[7] because it deviated from the D.C. Circuit's "understanding of the statute's intended incentive structure." App., *infra*, 60a, 64a.

The court derived its understanding of that "incentive structure" principally from *Ranbaxy Labs. Ltd.* v. *Leavitt*, 469 F.3d 120 (D.C. Cir. 2006). That case addressed the impact of patent delisting under the *pre-MMA* statutory scheme—that is, *before* Congress enacted the patent delisting "forfeiture event." *Ranbaxy* rejected FDA's interpretation of the pre-MMA statute to eliminate the basis for an award of generic exclusivity when a brand-name manufacturer delisted a challenged patent if the generic had not already been sued by the brand. *Id.* at 123. In such circumstances, *Ranbaxy* held, forfeiture of exclusivity was "inconsistent with the structure of the statute," *id.* at 125, because it "diminishe[d] the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book," *id.* at 126.

The *Teva* majority concluded that the MMA had done "nothing" to change the statutory incentive structure or to undermine the *Ranbaxy* decision.

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[7] See *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 842-843 (1984).

App., *infra*, 59a-60a. The court acknowledged FDA's contrary reading of the statute and purported to evaluate FDA's position "under the familiar two-part *Chevron* framework." *Id.* at 56a-57a. The court further acknowledged that FDA based its position on the MMA's addition of an explicit "forfeiture event" triggered by patent delisting and on the fact that "'the plain language of the statute contains no limitation on when delisting can occur.'" *Id.* at 58a (quoting *Teva* FDA Br. 44 (D.C. Cir. Oct. 16, 2009)). But the court concluded that Congress could not have meant to allow the brand-name manufacturer to "unilaterally deprive the generic of its exclusivity" by voluntarily delisting the challenged patent. *Id.* at 62a.

The court dismissed FDA's "argument that the plain language of the statute imposes no limit on the circumstances in which the agency may effectuate delisting requests," because "[p]recisely the same could have been said of the version of the statute that *Ranbaxy* addressed." App., *infra*, 62a. The court further claimed that brand-name manufacturers would voluntarily delist patents only when doing so would be "destructive" toward the statute's goal of encouraging generic competition. App., *infra*, 62a-63a. In the court's view, brand-name manufacturers would not delist a challenged patent to prevent claims of anti-competitive conduct or to avoid the expense or uncertainty of full-scale litigation (or for any other reason); rather, they would do so (and thereby expedite their own competition with *all* generic manufacturers) to discourage the filing of paragraph IV certifications with respect to future drugs. *Ibid.*

FDA petitioned for panel rehearing and rehearing *en banc*. FDA argued that the majority opinion in *Teva* was "fatally flawed because it condemns [FDA] for applying [the MMA's] explicit wording" and for heeding "Congress's finding that [180-day exclusivity under the pre-MMA statutory scheme] was being misused to thwart full competition." *Teva* FDA Reh'g Pet. (D.C. Cir. Apr. 5, 2010); see also *id.* at 3 ("The panel's * * * interpretation of the statute is not only contrary to the unambiguous text and Congress's deliberate rebalancing of competing goals, it squarely conflicts with this Circuit's message in other FDA decisions concerning the importance of fidelity to Congress's enactments."). FDA noted that, "[b]ecause all Hatch-Waxman cases can be filed in this Circuit (and most usually are), the panel majority's decision could be the last word on the substantial issues involved here." *Id.* at 15. Accordingly, FDA explained, the case was "exceptionally important" and "satisfie[d] the rigorous standards for *en banc* review." *Id.* at 3, 15. The D.C. Circuit denied the petition.

2. *Proceedings On Remand And Expiration Of The '075 Patent*

Shortly after the panel's decision, the parties discovered that the '075 patent had actually *expired* in March 2009 as a result of Merck's failure to pay the necessary maintenance fees to the Patent and Trademark Office. Teva then sought an order in the district court declaring that *neither* delisting nor expiration of the '075 patent had caused Teva to forfeit exclusivity. *Teva* Opp. to Motion To Amend Judgment at 4 (D.D.C. Mar. 23, 2010). Teva argued that the D.C. Circuit's opinion meant that any

"unilateral" action by the brand-name manufacturer resulting in removal of the challenged patent from the Orange Book could not affect the first applicant's right to exclusivity. The district court, however, concluded that the impact of patent expiration must be litigated "in a new lawsuit" filed after FDA had reached a decision directly addressing the impact of patent expiration. *Teva* Order Amending Judgment at 3 n.4 (D.D.C. Mar. 26, 2010).

The same day, FDA issued its decision addressing the expiration of the '075 patent—the decision directly at issue here. FDA first stated that, under the plain language of the statute as amended by the MMA, "patent expiration for any reason is a patent expiration forfeiture event." App., *infra*, 21a. "[P]ermitting the first applicant to retain exclusivity as to an expired patent," FDA explained, "requires FDA to take an action that is not sanctioned by the words of the statute." *Id.* at 25a. FDA thus declared that,

> if it were assessing this issue without reference to the *Teva* decision, it would find that, under the plain language of the statute, because the '075 patent will have expired by the time any ANDA referencing Cozaar or Hyzaar is ready for approval, any first applicant previously eligible for 180-day exclusivity as to the '075 patent forfeits that exclusivity.

Id. at 26a. FDA concluded, however, that the *Teva* decision precluded the forfeiture of exclusivity based on unilateral action by the brand-name manufacturer resulting in the removal of a challenged patent from the Orange Book. FDA therefore determined that, "consistent with the reasoning of the Court of Appeals, despite having been delisted by the patent

owner and having expired, the '075 patent nevertheless must be considered to remain a basis for 180-day exclusivity." *Id.* at 28a. Teva's exclusivity was set to begin on April 6, 2010.

3. ***Apotex* v. *Sebelius***

Four days after FDA issued its decision, Apotex and Roxane Laboratories filed suit in the United States District Court for the District of Columbia challenging the award of exclusivity to Teva. On April 2, 2010, the district court denied Apotex's motion for a preliminary injunction. App., *infra*, 4a-11a. The district court upheld FDA's conclusion that, despite the plain language of the MMA's forfeiture provisions, FDA was bound by the majority opinion in *Teva* to grant exclusivity to Teva. See *id.* at 9a ("The Court cannot find that the FDA was arbitrary or capricious when it politely expressed its disagreement with a D.C. Circuit decision * * * but nonetheless applied the reasoning of the Circuit to a different but, on these facts, closely related question.").

Apotex appealed and filed an emergency motion to stay the impending commencement of Teva's exclusivity period. The D.C. Circuit denied the motion, and Teva's exclusivity period began as ordered by FDA. On July 6, 2010, the D.C. Circuit issued a *per curiam* judgment affirming the district court's decision. App., *infra*, 1a-3a. Relying almost exclusively on *Teva*, the court of appeals reaffirmed its view that, in light of the statute's perceived "incentive structure," "Congress *could not* have intended a brand manufacturer's unilateral decision to cause the premature expiration of a patent (in the face of a generic applicant's challenge to the patent in

a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute." App., *infra*, 2a-3a (emphasis added).[8]

REASONS FOR GRANTING THE PETITION

This Court's immediate review is necessary to remedy fundamental and costly errors inflicted by the decision below. The Hatch-Waxman Act, as amended by the MMA, is largely responsible for the development of the multi-billion-dollar generic drug industry and the resulting benefits to health-care consumers. The 180-day exclusivity period is a key fulcrum point in the statutory scheme: Congress balanced that lucrative reward for first applicants with the need to promote full-scale competition *among* generics. Responding to anti-competitive abuses, the MMA adjusted that delicate equilibrium to limit more tightly the availability of exclusivity.

In ignoring that clear congressional command, the decision below did serious damage to a federal statute of the highest importance. In concrete terms, the decision below will confer massive anti-competitive advantages on drug companies (both generic and brand-name) that Congress did not authorize. In just the next several years, numerous major generic drugs are set to enter the market. If they do so under the erroneous decision below, consumers will bear

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[8] Teva's exclusivity period concluded on October 4, 2010. As the government acknowledged in seeking *en banc* review in the D.C. Circuit in *Teva*, that is no obstacle to further appellate review. See *Teva* FDA Reh'g Pet. 15 n.7 ("Even [in the event the exclusivity period has expired], the Court should rehear this matter under the 'capable of repetition, yet evading review' exception to the mootness doctrine.") (quoting *Del Monte Fresh Produce Co.* v. *United States*, 570 F.3d 316, 322-323 (D.C. Cir. 2009)).

billions of dollars in unnecessary and unintended costs.

Its practical importance aside, the D.C. Circuit's decision is plainly wrong as a matter of statutory interpretation. It does not seriously confront the statutory text, relying instead on the court's understanding of the statute's "intended incentive structure." It also errs in divining those "incentives," relying on a *pre*-MMA decision and, in turn, on the deeply flawed premise that brand-name manufacturers will work to frustrate the availability of generic exclusivity. The D.C. Circuit simply misunderstood that any manufacturer will prefer government-protected duopoly to wide-open competition.

Equally troubling, the D.C. Circuit did all of this under the guise of *step one* of *Chevron*, rejecting FDA's view that the statute draws no distinction between "unilateral" action and other action resulting in removal of a challenged patent from the Orange Book. This Court's immediate review is necessary to remedy these fundamental errors and the resulting damage to a vital federal statutory scheme.

I. The Question Presented Is Tremendously Important To The Generic Drug Industry And To Health-Care Consumers Nationwide

As the government has noted, the issue presented here is "exceptionally important." *Teva* FDA Reh'g Pet. 3. In practical terms, it controls the fate of billions of health-care dollars. If left undisturbed, the decision below will benefit brand-name manufacturers, who want nothing more than to see a first applicant win exclusivity and thereby delay full-scale competition with multiple generic manufacturers. It will also richly reward the generic manufacturer who wins a race to file a paragraph IV certification but is unable promptly to bring the generic drug to market.

What is more, first applicants have quickly learned how to leverage the initial exclusivity period into sustained market advantages that further impair full competition. The costs of delaying and then stifling full-scale generic competition are inevitably borne by health-care consumers. That is why Congress restricted the availability of exclusivity in the MMA, and that is why the D.C. Circuit's willingness to ignore that express congressional command warrants this Court's immediate review.

Enforcing the statutory scheme governing the generic drug industry is a matter of nationwide importance. Before the Hatch-Waxman Act's passage in 1984, generic drugs accounted for only about 12% of all prescriptions filled in the United States. See FDA, Greater Access to Generic Drugs (Jan. 2006) ("FDA Generics Report"), *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm. Today, by contrast, about 75% of all U.S. prescriptions are filled with generic drugs (not to mention over-the-counter generics), and domestic sales of generic drugs average more than $50 billion per year. Jonathan D. Rockoff, *Prescription-Drug Sales Rise 5.1%*, Wall Street Journal, Apr. 2, 2010; Generic Pharmaceutical Ass'n, *Facts at a Glance*, *available at* http://www.gphaonline.org/about-gpha/about-generics/facts (last visited Sept. 27, 2010). Annual sales of a single blockbuster generic drug can exceed $1 billon.[9] The industry has flourished largely because Congress and FDA have established, monitored, and revised a comprehensive statutory

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[9] Sales for the generic form of the heartburn medicine Prilosec, for example, exceeded $1.1 billion in 2009. See "omeprazole" at Drug Topics, *2009 Top 200 Generic Drugs by Retail Dollars* (June 17, 2010), *available at* http://drugtopics.modernmedicine.com/drugtopics/data/articlestandard/drugtopics/252010/674976/article.pdf.

and regulatory regime encouraging its development in the public interest.

The success of that venture has had profoundly positive consequences for virtually every American. Generic drugs generally cost a fraction of the price for the equivalent brand-name drug and thus "play a key role in making health care more affordable." FDA Generics Report. A recent study reported that generic drugs "saved the nation's health care system more than $824 billion dollars" over the last ten years, with savings of $139.6 billion in 2009 alone. IMS Health & Generic Pharmaceutical Ass'n, *Savings Achieved Through the Use of Generic Pharmaceuticals 2000-2009* at 1 (July 2010) ("IMS Report"), *available at* http://www.gphaonline.org/sites/default/files/GPhA%20Savings%20Study%20Book%20Updated%20Web%20FINAL%20Jul23%2010_0.pdf.

The 180-day exclusivity period is a crucial—and carefully calibrated—facet of the statutory scheme fostering generic competition. See FTC Statement ("The second significant component of Hatch-Waxman is the '180-day period of exclusivity.' * * * Through this 180-day provision, the Amendments provide an increased incentive for companies to challenge patents and develop alternatives to patented drugs."). Exclusivity offers generic manufacturers an incentive to challenge dubious patents listed by brand-name manufacturers in the Orange Book, thus encouraging the earlier introduction of generic drugs. But exclusivity is also *anti*-competitive, because "the generic applicant has the potential to reap the reward of marketing the only generic product (and, thus, to charge a higher generic price until more generic products enter)." *Ibid.* Understanding the tremendous rewards at stake is necessary to appreciate fully the magnitude of the D.C. Circuit's error in rejecting Congress's choice to pre-

scribe a specific balance between those contending objectives.

Winning a 180-day exclusivity period for even a single drug may be "worth several hundred million dollars" to a generic manufacturer. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006). That is because the generic manufacturer must compete only with the brand-name manufacturer (and vice versa), resulting in markedly higher duopoly pricing during the exclusivity period. Indeed, it is well documented that the vast majority of the cost savings offered by generics emerge only when there is full competition between multiple generic manufacturers. FDA has reported that, "[o]n average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer"—about six percent. FDA, *Generic Competition and Drug Prices*, *available at* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm (last visited Sept. 27, 2010). "[T]he appearance of a second generic manufacturer," however, "reduces the average generic price to nearly half the brand name price. * * * For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower." *Ibid.* Exclusivity thus gives the generic manufacturer a significant period of sales at artificially inflated prices.

What is more, the benefits of the 180-day exclusivity award often last well beyond the exclusivity period. That is due in part to the presence of pharmacy benefit managers (PBMs), which "play a critical role in managing prescription drug benefits," GAO,

Federal Employees' Health Benefits 1 (Jan. 2003), *available at* http://www.gao.gov/new.items/d03196.pdf, and other large-volume customers. For example, PBMs are hired by health-care plans to develop an approved list of drugs for plan participants and to negotiate with drug manufacturers to supply those drugs. These contracts are usually long-term, often running for two or three years. A manufacturer that is the exclusive source of a newly available generic drug thus has the opportunity to become the PBMs' supplier for far longer than the initial 180 days. And the generic manufacturer is also likely to use that leverage to become the PBMs' supplier for *other* generic drugs. Accordingly, "the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants." *Mova Pharmaceutical Corp.* v. *Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (internal quotation marks omitted).

Exclusivity is good news for brand-name manufacturers, too. See Jeremiah Helm, *The Patent End Game: Evaluating Generic Entry into a Blockbuster Pharmaceutical Market in the Absence of FDA Incentives*, 14 MICH. TELECOMM. & TECH. L. REV. 175, 190 (2007) ("the grant of exclusivity * * * also provides a substantial benefit to the branded pharmaceutical maker"). The higher the price charged by the generic manufacturer, the less downward price pressure the brand-name manufacturer faces. Almost any delay in reckoning with competition from multiple generic manufacturers results in more dollars for brand-name manufacturers. As explained in more detail below (*infra* pp. 32-34), the D.C. Circuit failed to appreciate this basic point, but the economic reality is inescapable: Exclusivity for one generic manufactur-

er means a much softer landing for the brand-name manufacturer.

These costs, of course, are ultimately borne by health-care consumers in the form of higher drug prices. Evidence suggests that awarding market exclusivity for a single, widely prescribed drug can leave consumers with a tab running into the billions of dollars. One commentator has estimated that a one-year delay in the entry of generic competition for certain widely prescribed drugs "represents, under conservative assumptions, a transfer from consumers to producers of about $14 billion." C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 650 (2009). Because duopoly pricing exists during the 180-day exclusivity period, and such prices are (by FDA's estimate) only six percent lower than the brand-name monopoly price, the costs to consumers are massive. See also Medco, *2010 Drug Trend Report* 6, *available at* http://www.drugtrend.com/art/drug_trend/pdf/DT_Report_2010.pdf (last visited Sept. 27, 2010) ("In recent years, 6-month exclusivity in generic marketing (which keeps generic prices temporarily high) has tempered the rate at which plan sponsors realize the full savings potential" of shifting patients to generic drugs.).

Because exclusivity is such a rich reward, it is a crucial lever in the larger statutory scheme encouraging full generic competition. Accordingly, when experience under the original Hatch-Waxman Act showed the potential for abuse of the exclusivity provisions and highlighted the steep costs exclusivity can impose on consumers, Congress deliberately

pared back its availability in the MMA. Indeed, some questioned whether exclusivity should be eliminated altogether, because the now-powerful generic drug industry no longer needed such strong incentives to challenge brand-name drug manufacturers. See 148 Cong. Rec. S7,349 (daily ed. July 25, 2002) (Sen. Hatch) ("Frankly, I think we need more public discussion and debate about the wisdom of retaining—lock, stock, and barrel—the old 180-day exclusivity award."). In the end, Congress decided to enumerate specific "forfeiture events" that limit a first applicant's entitlement to exclusivity. The decision below ignores that deliberate legislative choice and thus disrupts this carefully calibrated statutory scheme

II. The Issue Is Recurring And Warrants Immediate Review

The availability of generic exclusivity in the wake of "unilateral" action by a brand-name manufacturer to remove a challenged patent from the Orange Book is a recurring question that merits this Court's immediate review. Generic manufacturers continue to file paragraph IV certifications in large numbers, and brand-name manufacturers continue to delist challenged patents rather than face allegations of anti-competitive conduct or costly patent litigation. And, as the government has acknowledged, the decision below is almost surely the *de facto* final word on the subject. Delaying resolution of this question will force consumers to bear billions of dollars in costs that Congress never intended.

This issue has arisen repeatedly in recent years, and the decision below will have widespread effect if left undisturbed. Under the pre-MMA statutory

scheme, FDA refused to award exclusivity to first applicants when the challenged patent had been delisted without litigation. FDA applied that rule on numerous occasions and to many significant drugs. See FDA Ranbaxy Decision Letter 18-19 (Oct. 24, 2005) (FDA Docket No. 2005-P-0008) (explaining that FDA had already "delisted patents for Paxil (paroxetine hydrochloride), Serzone (nefazadone), Zyprexa (olanzapine), and Detrol (tolterodine)"). In just the few years since the MMA's enactment, FDA has addressed the impact of patent delisting on exclusivity for four major brand-name drugs where the manufacturer "unilaterally" caused the removal of a challenged patent from the Orange Book. Those drugs alone represent nearly two billion dollars in annual sales.[10]

Many more are coming down the pike: By our count, there are 27 patents for brand-name drugs—including several blockbusters—for which ANDAs including paragraph IV certifications have been filed and the challenged patent has been delisted or allowed to expire. See Apotex Reply to Opp. to Motion For Prelim. Inj. at 8 & n.3 (D.D.C Apr. 1,

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[10] FDA determined, for example, that patent delisting forfeited generic exclusivity for the glaucoma drug COSOPT, which had annual sales of approximately $337 million, and for the diabetes drug Precose, which had annual sales of approximately $34 million. See CVS/Caremark, *Generic Prospective Pipeline Summary* (June 12, 2009), *available at* http://www.khpa.ks.gov/sehp/download/BenDescr2009/2009GenPipelineSum.pdf.
Hyzaar and Cozaar, the two brand-name losartan drugs at issue here, have combined annual sales of approximately $1.6 billion. See Teva press release (Apr. 9, 2010), *available at* http://www.medicalnewstoday.com/articles/184871.php (citing IMS sales data).

2010). Some of these arise under the pre-MMA statute, which governs ANDAs filed before 2003,[11] but most are subject to the MMA's forfeiture provisions. If the decision below is allowed to stand, FDA will have no choice but to award exclusivity in many of these cases in spite of its wholly correct, and deference-worthy, conclusion that the statute does not authorize it.

The D.C. Circuit and the district court—which reached opposite conclusions—are the only courts to have addressed this issue, but that is neither surprising nor a reason to delay review. As the government has correctly acknowledged, because "all Hatch-Waxman cases can be filed in [the D.C. Circuit] (and most usually are), the panel majority's decision could be the last word on the substantial issues involved here." *Teva* FDA Reh'g Pet. 15. Indeed, the government understated the matter slightly to note that the D.C. Circuit is "the usual forum for these disputes," *id.* at 3. The D.C. Circuit has decided 11 cases concerning FDA's interpretation of the Hatch-Waxman Act's 180-day generic exclusivity provision. Only one published case from another circuit directly addresses FDA's interpretation of the 180-day exclusivity provision, *Mylan Pharmaceuticals, Inc.* v. *FDA*, 454 F.3d 270, 271 (4th Cir. 2006), and that

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[11] Even those drugs still governed by the pre-MMA statute will potentially benefit from a reversal of the decision below. While the most obvious problem with the court of appeals' analysis is its rejection of the plain text of the MMA's forfeiture provisions, the court was also wrong to claim that the *pre*-MMA "incentive structure" required the award of exclusivity in these circumstances.

opinion closely tracks a related D.C. Circuit decision.[12]

What is more, the D.C. Circuit's conclusion that Teva's lawsuit seeking a declaration of its entitlement to exclusivity before FDA had rendered a final decision was ripe likely will give first applicants the means to file any such future actions in D.C. to take advantage of this rule. By contrast, it is unclear whether a generic competitor of the first applicant would be able to bring suit elsewhere—here, the district court denied Apotex's attempt to intervene in Teva's lawsuit because FDA had not yet granted Apotex tentative approval to market the drug, and the D.C. Circuit declined to address that issue on appeal. It is thus exceedingly unlikely that a split will develop on this issue.

Meanwhile, the meter is running. The Federal Trade Commission estimates—conservatively—that products with roughly $90 billion dollars in sales were subject to live paragraph IV challenges at the end of 2008. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 9 (Jan.

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[12] The Federal Circuit also considers Hatch-Waxman issues from time to time when those issues arise in patent litigation, but the Federal Circuit generally cannot address claims regarding Hatch-Waxman statutory construction and FDA rulemaking. See, *e.g.*, *Minnesota Mining & Mfg. Co.* v. *Barr Labs., Inc.*, 289 F.3d 775, 783 n.4 (Fed. Cir. 2002) (refusing to resolve claims seeking "improper judicial enforcement of the provisions of the Hatch-Waxman Amendments, outside of the context of an APA suit"). The Federal Circuit did address FDA rules regarding Orange Book listings in *Apotex, Inc.* v. *Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), but in that case the court simply upheld FDA's policy of refusing to review Orange Book listings independently.

2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. Another report estimates that "[d]rugs with total 2009 U.S. sales of about $50 billion could lose patent protection over the next 3 years, expanding in an almost unprecedented manner the market for lower-cost generics." Medco, *supra*, at 42. Some of these are truly blockbuster drugs: "Six of the 10 current largest-selling drug products are expected to encounter generic competition" in the next few years "including the top two: Pfizer's $14 billion cholesterol fighter Lipitor® and the blood clot preventer Plavix® by Bristol-Myers Squibb." IMS Report at 3-4. This Court's immediate review is therefore necessary to avoid the billions of dollars in costs associated with the erroneous award of exclusivity with respect to even one of these drugs.

This Court has not hesitated to grant certiorari where, as here, it confronts issues that "concern the construction of a major federal statute." *United States* v. *Donovan*, 429 U.S. 413, 422 (1977). Certiorari is often granted even in the absence of a circuit split when a court of appeals fumbles a question of first impression regarding the interpretation of a federal statute. See, *e.g.*, *Household Credit Services, Inc.* v. *Pfennig*, 541 U.S. 232, 235 (2004); *American Federation of Musicians* v. *Wittstein*, 379 U.S. 171, 175 (1964); see also EUGENE GRESSMAN ET AL., SUPREME COURT PRACTICE 267 (9th ed. 2007) (for many cases involving "the construction and application of acts of Congress * * * the importance of the issue is the major basis for securing review"). On a federal statutory issue of such profound importance and widespread concern, it is both unnecessary and ill advised to delay review.

That is especially true because, as we briefly explain below, the D.C. Circuit got this question dead wrong.

III. The Decision Below Is Erroneous

Three errors in the court of appeals' analysis are particularly deserving of this Court's immediate review.

First and foremost, the D.C. Circuit failed to heed the most basic tenet of statutory interpretation that "courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Connecticut Nat'l Bank* v. *Germain*, 503 U.S. 249, 253-54 (1992); see also, *e.g.*, *Carcieri* v. *Salazar*, 129 S. Ct. 1058, 1063 (2009). The MMA specifically identified patent delisting as a "forfeiture event" and gave no indication that it would not apply if that delisting was the result of "unilateral" action by the brand-name manufacturer. To the contrary, the text states explicitly that forfeiture is triggered if the patent is "withdrawn ***by*** the [brand-name manufacturer]." 21 U.S.C. § 355(j)(5)(D)(i)(I) (double emphasis added). A patent delisted "by" the brand-name manufacturer most naturally means one that is delisted "unilaterally." At the very least, it must *include* unilateral delisting.

The D.C. Circuit gave no meaningful consideration to that text. Rather, the court noted simply that it had already crossed this bridge in *Ranbaxy* and saw no reason to turn back:

> The argument that the plain language of the statute imposes no limit on the circumstances in which the agency may effectuate delisting requests fails. Precisely the same could have been said of the version of the statute that *Ranbaxy*

> addressed, and we nevertheless concluded that its structure precluded an FDA rule allowing the agency "to delist a patent upon the request of the [brand manufacturer]" when the delisting would rob the generic maker of earned exclusivity.

App., *infra*, 62a. But *Ranbaxy* concerned the *pre*-MMA version of the statute, before Congress expressly enumerated delisting as a forfeiture event without limitation. See *Mobil Oil Corp.* v. *Higginbotham*, 436 U.S. 618, 625 (1978) ("There is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted."). Accordingly, relying on *Ranbaxy* to settle the question of the *post*-MMA statute's plain language wholly misses the point.

The statute is equally clear on the effect of patent expiration. It declares that the "180-day exclusivity period * * * *shall* be forfeited," 21 U.S.C. § 355(j)(5)(D)(ii) (emphasis added), when "[a]ll of the patents as to which the applicant submitted a [Paragraph IV] certification qualifying it for the 180-day exclusivity period *have expired*," *id.* § 355(j)(5)(D)(i)(VI) (emphasis added). Yet again, there is no mention of *why* a patent has expired, much less a textual requirement that the patent must have expired of "natural causes" rather than by virtue of the holder's failure to pay the required fees. There is simply no basis in the text for the D.C. Circuit's holding that forfeiture does not occur if expiration is the result of "unilateral" action by the patent holder.

The D.C. Circuit not only ignored those clear textual commands but also failed to give serious

consideration to FDA's longstanding position that unilateral action can result in the forfeiture of exclusivity. While paying lip service to "the familiar two-part *Chevron* framework," App., *infra*, 57a, the court made no meaningful attempt to explain how the statute's text foreclosed FDA's position. Instead, the court again retreated to its pre-MMA decision in *Ranbaxy* and declared that it "s[aw] nothing in the [MMA] that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event." App., *infra*, 64a. "For that reason," the court concluded, FDA's position "fails at *Chevron* step one." *Ibid.* But relying on a previous interpretation of the "incentive structure" of a prior version of a statute is not the inquiry that *Chevron* step one demands. Cf. *Nat'l Cable & Telecomms. Ass'n* v. *Brand X Internet Servs.*, 545 U.S. 967, 980-986 (2005) (even an agency's own change of position requires fresh judicial inquiry about the meaning of a statute whose administration is entrusted to the agency).

The D.C. Circuit's terse dismissal of FDA's position is all the more remarkable because Congress intended the MMA to limit the availability of exclusivity. The MMA responded, in part, to evidence that "brand and generic companies * * * abused [the 180-day] exclusivity period." 149 Cong. Rec. S15,746 (daily ed. Nov. 24, 2003) (Sen. Schumer). How could the enumeration of specific "forfeiture events" not at least raise the specter of ambiguity as to whether "unilateral" delisting or expiration would trigger forfeiture? Indeed, Congress enacted the MMA *after* FDA had articulated its view that a brand-name manufacturer's delisting of a challenged patent—unilateral or otherwise—could forfeit the first

applicant's exclusivity. If Congress had intended the opposite, as the D.C. Circuit later concluded in *Ranbaxy* and again in the decisions below, Congress would have said so when promulgating the MMA. It did not, and the D.C. Circuit was wrong to "override that choice." *Whitfield* v. *United States*, 543 U.S. 209, 217 (2005). Indeed, as the D.C. Circuit would have it, Congress witnessed FDA *wrongly* interpreting the statute without regard to whether a delisting action was "unilateral" and then specifically enumerated no fewer than six "forfeiture events" without limiting them to non-unilateral conduct. That defies common sense; at the very least, it introduces a profound ambiguity into the statute and makes the D.C. Circuit's ruling on *Chevron* step one entirely implausible.

Even if the statute's "incentive structure" could somehow trump its plain text, the D.C. Circuit fundamentally misunderstood the operative economic realities. The D.C. Circuit believed that, under FDA's reading of the statute, brand-name manufacturers would deliberately "pull the rug from under the paragraph IV certification" as a way to combat generic competition. App., *infra*, 35a. Thus, the D.C. Circuit's theory goes, brand-name manufacturers view unilateral removal of a patent from the Orange Book as a way to *hinder* competition. That is wrong.

For starters, the D.C. Circuit's theory overlooks the obvious fact that removing a challenged patent—unilaterally or otherwise—*expedites* full generic competition for that drug. Here, for example, Merck's decision to allow the '075 patent to expire meant that it faced generic competition in sales of Cozaar and Hyzaar beginning in 2010 instead of 2014. For many

drugs, removal of the challenged patent will cost the brand-name manufacturer hundreds of millions of dollars in lost sales. And any discouraging effect such action might have on generic manufacturers would be, at best, indirect and delayed. The one sure result of "unilateral" delisting or expiration is that brand-name manufacturers will face full-on generic competition sooner.

In fact, if a challenged patent is to be removed from the Orange Book (whether by voluntary action of the brand-name manufacturer or for some other reason), brand-name manufacturers will very much hope that one generic manufacturer wins exclusivity. That is because, as explained above (*supra* pp. 22-23), the brand-name manufacturer stands to make significantly more money competing with just one generic than with many. Recall that prices tend to drop only about six percent off the brand-name monopoly price during the generic exclusivity period, but they plummet 80% when multiple generics enter the market. See *supra* p. 21. Brand-name manufacturers reap extraordinary benefits from the competition-limiting effects of exclusivity, so they are highly unlikely to participate in its untimely demise.

Brand-name manufacturers unilaterally seek removal of a challenged patent from the Orange Book, *not* to frustrate generic competition, but because there are other powerful incentives to do so. A principal driver is the fear of being charged with anti-competitive conduct for attempting to prolong the monopoly resulting from legitimate patents by also listing a bogus one. In recent years, the FTC has made significant efforts to punish companies for such

conduct.[13] As a result, when an ANDA applicant makes a paragraph IV certification challenging a listed patent, the brand-name manufacturer must take a long, hard look at whether its claim will withstand government scrutiny.

Even without fear of government action, brand-name manufacturers must consider the practical costs of asserting a bogus patent. There is little sense in such circumstances in spending millions of dollars to sue a generic manufacturer for infringement or to defend a declaratory judgment action by the generic manufacturer. If a patent has a truly weak connection to a brand-name drug, the brand-name manufacturer faces significant potential costs for maintaining it. The best course is often to seek its removal from the Orange Book, thus achieving precisely the result that Congress intended.

Finally, even if the D.C. Circuit were correct that preserving exclusivity automatically furthered the larger goal of promoting generic competition, that is not a reason to disregard the statute's plain language. It is axiomatic that "no legislation pursues its

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[13] See FTC Response to IVAX Citizen Petition 7 (Apr. 5, 2005) (FDA Docket No. 2005-P-0008) ("The Commission has brought a number of enforcement actions involving the improper listing of patents in the Orange Book by brand-name companies, which allegedly delayed generic drug approval and resulted in consumer harm."); FTC Statement ("Our 'second generation' of enforcement activities has involved allegations that individual brand-name manufacturers have delayed generic competition through the use of improper Orange Book listings * * *."). Bristol-Myers Squibb and Biovail, for example, entered into consent agreements with the FTC in which they agreed, among other things, to cease listing improper patents in the Orange Book. *Bristol-Myers Squibb Co.*, 135 F.T.C. 444 (2003); *Biovail Corp.*, 134 F.T.C. 407 (2002) (consent orders).

purposes at all costs." *Rodriguez* v. *United States*, 480 U.S. 522, 525-526 (1987) (per curiam). Rather, "[d]eciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Id.* at 526 (emphasis in original). Even if the anti-competitive effects that accompany generic exclusivity are merely short-term, it is up to Congress—not the courts—to decide how much encouragement to offer the generic drug industry. Indeed, there is overwhelming evidence that Congress has been particularly successful in this endeavor: In the quarter-century since the Hatch-Waxman Act was passed, generic drugs have proliferated and saved consumers billions of dollars, while brand-name manufacturers have continued to make groundbreaking and lifesaving discoveries. Courts have no business tinkering with such a carefully calibrated legislative balance.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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OCTOBER 2010

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 10-5094 **September Term 2009**

1:10-cv-00517-RMC
1:10-cv-00521-RMC

Filed On: July 6, 2010

Apotex, Inc.,

Appellant

Roxane Laboratories, Inc., Civil Action No. 10-521,

Appellee

v.

Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services, et al.,

Appellees

No. 10-5108

Roxane Laboratories, Inc.,

Appellant

v.

United States Food and Drug Administration, et al.,

Appellees

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

BEFORE: Tatel, Griffith, and Kavanaugh, Circuit Judges

JUDGMENT

These consolidated appeals were considered on the record from the United States District Court for the District of Columbia and on the briefs filed by the parties. *See* Fed. R. App. P. 34(a)(2); D.C. Cir. Rule 34(j). It is

ORDERED AND ADJUDGED that the district court's order filed April 2, 2010, denying motions for a preliminary injunction, be affirmed. For a preliminary injunction to issue "a litigant must show '(1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction were not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction.'" *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (quoting *CityFed Financial Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995)).

The district court correctly concluded that appellants failed to show a substantial likelihood of success on the merits. When the Hatch-Waxman Act's forfeiture provisions are viewed in the context of the statute's incentive structure, it becomes clear that

Congress could not have intended a brand manufacturer's unilateral decision to cause the premature expiration of a patent (in the face of a generic applicant's challenge to the patent in a paragraph IV certification) to strip the first generic applicant of the 180-day period of marketing exclusivity granted by the statute. *See Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1317–18 (D.C. Cir. 2010). We will thus affirm the district court's decision to deny appellants' motions for a preliminary injunction. *See Apotex, Inc. v. FDA*, 449 F.3d 1249, 1253–54 (D.C. Cir. 2006).

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The Clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or petition for rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. Rule 41.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Michael C. McGrail
Deputy Clerk

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

APOTEX, INC., *et al.*

Plaintiffs,

v.

Civil Action
No. 10-517 (RMC)

KATHLEEN SEBELIUS, Secretary, Department of Health and Human Services, *et al.*,

Defendants.

MEMORANDUM OPINION

The question presented is whether the U.S. Food and Drug Administration ("FDA") was arbitrary and capricious when it applied the reasoning of a recent D.C. Circuit opinion, with which the FDA disagrees, to the facts of the instant dispute when time is of the essence and the Solicitor General has not yet decided whether to move for rehearing.

Plaintiffs in this consolidated case, Apotex, Inc. ("Apotex"), and Roxane Laboratories, Inc. ("Roxane"), are two manufacturers of generic drugs. They assert that it is the height of arbitrariness for the FDA to explain its own reading of the "clear" language of the statute and then apply the contrary reasoning of the Circuit, with the effect of allowing a third generic

drug manufacturer to get 180 days of marketing exclusivity starting, perhaps, as early as April 6, 2010. The Court disagrees. On this record and with these facts, the FDA recognized that it is bound to follow the Circuit opinion until and unless it gets that opinion modified or reversed. The parties' recourse is to the Circuit.

I. BACKGROUND

A quick summary of a lot of litigation should suffice to present the current controversy. Readers are directed to the Circuit's decision, *Teva Pharms. USA, Inc. v. Sebelius*, 595 F. 3d 1303 (D.C. Cir. 2010), for details.

Teva Pharmaceuticals USA, Inc., is a generic drug manufacturer. It filed an abbreviated new drug application ("ANDA") with the FDA and claimed that its generic versions of Cozaar and Hyzaar (losartan) did not infringe the '075 patent held by Merck, the brand name drug manufacturer. Because Teva's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), if the FDA approved the ANDA, Teva would have 180 days of marketing exclusivity for its generic drugs immediately upon expiration of Merck's last related patent. *See id.* § 355(j)(5)(B)(iv)(I). Instead of suing Teva for patent infringement, Merck responded by "delisting" the patent with the FDA. *See id.* § 355(j)(5)(D)(i)(I)(bb)(CC). As interpreted by the FDA, the Food, Drug, and Cosmetic Act, as amended (codified in relevant part at 21 U.S.C. § 355), provides for forfeiture of exclusivity if the first ANDA filer (here, Teva) fails to market its product within a

specified time after patent delisting. *See Teva Pharms. USA, Inc., v. Sebelius*, 638 F. Supp. 2d 42, 48 (D.D.C. 2009), *rev'd and remanded by* 595 F. 3d 1303 (D.C. Cir. 2010). It is undisputed that Teva did not go to market within that time period after Merck delisted the '075 patent, since the FDA had not approved Teva's ANDA and FDA did not publicize that Merck had withdrawn the patent from FDA's list. The FDA determined that Teva had thus forfeited its right to exclusivity and this Court agreed. *See generally id.*

The Circuit did not. Holding that the structure of the Act does not permit the unilateral action of a patent holder to deprive a first ANDA applicant of its short-term marketing exclusivity, the Circuit reversed and directed this Court to give relief to Teva. *Teva*, 595 F.3d at 1319 ("We therefore reverse the judgment of the district court, but, as the court has yet to address the appropriateness of each form of relief that Teva has sought, we remand for further proceedings....").

On remand, the FDA informed the Court that it had learned that the Merck '075 patent had actually expired prior the filing of Teva's lawsuit, due to Merck's failure to pay maintenance fees to the U.S. Patent and Trademark Office after it "delisted" the patent. FDA argued that patent expiration is another and separate basis on which, under the Act, it might be found that Teva had forfeited marketing exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(VI). FDA advised the Court that it had posted a notice at www.regulations.gov in Docket No. FDA-2010-N-0134, and was receiving comments on how it should

interpret § 355(j)(5)(D)(i)(VI), under which exclusivity may be forfeited if a patent expires. FDA promised to make its determination no later than March 26, 2010. FDA urged the Court to withhold its remedy order for Teva until after FDA decided the question of statutory interpretation. However, because Teva had persuaded the Circuit to expedite its appeal and the mandate, in light of the anticipated expiration of the last Merck patent on April 6, 2010 (except for Merck's failure to maintain the patent), this Court issued its order on relief on March 16, 2010. *See* Dkt. # 28. On the FDA's motion to amend the order, the Court issued its final order on March 26, 2010. *See* Dkt. # 33.

On March 26, 2010, as predicted, FDA issued a letter to ANDA applicants and notified them that, while it disagreed with the Circuit opinion, it had applied the Circuit's reasoning to answer "no" to the question of whether a brand name drug manufacturer could unilaterally cause its patent to expire and, thus, force a forfeiture of a first ANDA applicant's right to marketing exclusivity for 180 days. *See* Dkt. # 34. Therefore, the FDA announced, it would not prevent the first ANDA applicant, Teva, from enjoying its 180-day marketing exclusivity for its generic losartan drugs, and would not approve any other ANDA application during that time period. *Id.* The consolidated petitions for a preliminary injunction immediately followed in an attempt to prevent FDA's approval of Teva's ANDA.

Apotex and Roxane are both generic drug manufacturers who compete with Teva. Each Plaintiff has a pending ANDA for generic versions of

Cozaar and Hyzaar and each has been preparing to begin marketing after April 6, 2010. Apotex participated as *amicus curiae* in the Teva suit; it was granted intervenor status on remand. Apotex filed the instant complaint on March 30, 2010, along with a proposed very short briefing schedule, with which the FDA agreed. Teva filed a motion to intervene on the same day. The Court adopted the briefing schedule and granted Teva intervenor status. Roxane filed its separate suit on March 30; it agreed to the same briefing schedule and moved, without opposition, to consolidate the cases. The Court granted both motions. This abbreviated opinion recognizes the parties' need for a quick decision.

II. LEGAL STANDARDS

There are four familiar factors that govern whether preliminary injunctive relief should be awarded and they are analyzed on a sliding scale. In other words, the stronger the case on one point, the lesser the evidence needs to be on another. In order to obtain a preliminary injunction, a party must demonstrate that: (1) it has a likelihood of success on the merits; (2) it will suffer irreparable injury in the absence of preliminary relief; (3) other interested parties will not be substantially injured if the requested relief is granted; and (4) granting such relief would serve the public interest. *See Katz v. Georgetown Univ.*, 246 F.3d 685, 687-88 (D.C. Cir. 2001); *Biovail Corp. v. FDA*, 448 F. Supp. 2d 154, 155 (D.D.C. 2006). The likelihood of success requirement is the most important of these factors. *Id.* "Without any probability of prevailing on the merits, the Plaintiffs' purported injuries, no matter how

compelling, do not justify preliminary injunctive relief." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999). "[A] party seeking a preliminary injunction must demonstrate...'a likelihood of success on the merits,'" not merely the existence of "questions 'so serious, substantial, difficult and doubtful, as to make them fair ground for litigation.'" *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008).

Review of final agency action is conducted under the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* FDA's March 26, 2010 letter to ANDA applicants for generic versions of Cozaar and Hyzaar (losartan) drug products constituted final agency action as it relates to Plaintiffs and is, therefore, subject to court review. The FDA does not argue otherwise. Under the APA, a court will uphold agency action unless it is arbitrary or capricious or inconsistent with the law. *See* 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001).

III. ANALYSIS

The Court cannot find that the FDA was arbitrary or capricious when it politely expressed its disagreement with a D.C. Circuit decision that had ruled against the agency, but nonetheless applied the reasoning of the Circuit to a different but, on these facts, closely related question. Given the facts and law in this record, the Court finds that Plaintiffs have a very slim chance of success on the merits. This factor does not support issuance of a preliminary injunction.

The irreparable harm predicted by Plaintiffs is not to be ignored. Their drug products would be precluded from competing with Teva's for 180 days and, according to Plaintiffs, that head start would have a multi-million dollar consequence that could not be recovered. FDA points out that "[m]ere injuries, however substantial, in terms of money, time and energy necessarily expended," do not constitute irreparable harm. *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). "[F]inancial harm alone cannot constitute irreparable injury unless it threatens the very existence of the movant's business," *Sociedad Anonima Vina Santa Rita v. Dep't of Treasury*, 193 F. Supp. 2d 6, 14 (D.D.C. 2001), a standard neither Plaintiff meets. Plaintiffs also argue, however, that consumers will suffer from significantly higher prices if Teva's generics do not have immediate generic competition. This latter argument is forestalled by the Circuit's finding that the structure of the Act indicates a clear pro-consumer congressional intent to reward a first ANDA applicant that challenges a brand manufacturer's patent with short-term marketing exclusivity, as a matter of law and public policy. This factor counsels against an injunction.

As to harm to others, an injunction as sought by Plaintiffs would certainly injure Teva and would prevent public access to any generic of these drugs. This factor does not support issuance of an injunction.

The fourth factor to consider is the public interest. Plaintiffs argue that consumers are entitled to brisk competition among generic drug manufacturers so

that they will enjoy lower prices. The argument is contrary to the teaching of *Teva*, where the Circuit described the structure of the statute as pro-consumer because the first ANDA filer is encouraged by the reward of exclusivity to hurry generic drugs to market. *Teva*, 595 F.3d at 1318 ("The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device....The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick their necks out....").

Thus, this factor also fails to support preliminary injunctive relief.

IV. CONCLUSION

The Court will deny Plaintiffs' motions for a preliminary injunction [Dkt. # 4 in No. 10-517; Dkt. # 4 in No. 10-521]. The Court agrees that FDA properly followed the logic of the D.C. Circuit's decision in *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303. A memorializing order accompanies this memorandum opinion.

Date: April 2, 2010

/s/
ROSEMARY M. COLLYER
United States District Judge

APPENDIX C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

[March 26, 2010]

SENT VIA TELEFAX

Docket No. FDA-20l0-N-0134

Dear ANDA Applicants:

This letter addresses whether the March 4, 2009 expiration of U.S. Patent No. 5,608,075 ('075 patent) affects the first applicant's eligibility for l80-day exclusivity for generic versions of Merck's Cozaar and Hyzaar drug products, and supplements the March 11, 2010 letter to ANDA applicants that was posted at www.regulations.gov in Docket No. FDA-20l0-N-0134. As explained below, in light of the Court of Appeals' decision in *Teva Pharms., USA, Inc. v. Sebelius*, No. 09-5281 (D.C. Cir. Mar. 2, 2010) ("*Teva* slip op."), we have concluded that the expiration of the '075 patent does not result in a forfeiture of the first applicant's eligibility for exclusivity for ANDAs referencing Cozaar and Hyzaar.

Background

FDA has pending before it ANDAs referencing Cozaar (losartan potassium) Tablets and Hyzaar (losartan potassium and hydrochlorothiazide)

Tablets. Among the patents submitted to FDA for Cozaar and Hyzaar, and thus relevant to the approval date for these ANDAs, is the '075 patent. FDA's Orange Book shows that the '075 patent was submitted by Merck, and that Merck later requested delisting of the patent. Merck has also recently informed FDA that the expiration date for the '075 patent should be revised from March 4, 2014, to March 4, 2009.[1] The Orange Book currently displays the March 4, 2009 expiration date for the '075 patent.

The timing of approval of ANDAs referencing Cozaar and Hyzaar will be affected by, among other things, any 180-day exclusivity under section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (the Act) available to a first applicant to challenge the '075 patent.[2] Under the Act, as amended by the MMA, a 180-day exclusivity period will not delay approval of any ANDA referencing Cozaar or Hyzaar if the exclusivity has been forfeited by the first applicant. See section 505(j)(5)(D)(i). The

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[1] Apotex notified FDA on March 9, 2010, that records of the U.S. Patent and Trademark Office (PTO) showed that the '075 patent had expired no later than March 30, 2009, due to non-payment of fees. Pursuant to the procedure described in 21 C.F.R. § 314.53(f), FDA sought information from Merck regarding the correct expiration date for the '075 patent. By letters of March 12, 2010, Merck stated that the correct expiration date for the '075 patent is March 4, 2009.

[2] The 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar is governed by section 505(j)(5)(B)(iv) and related provisions, as modified by the Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) (the MMA).

delisting of the '075 patent by Merck and the March 4, 2009 patent expiration date implicate two distinct 180-day exclusivity forfeiture provisions in the Act, sections 505(j)(5)(D)(i)(I) and (VI), respectively.

Delisting of the '075 Patent

The U.S. Court of Appeals for the D.C. Circuit recently considered the effect of the delisting of the '075 patent on a first applicant's claim to 180-day exclusivity arising from a paragraph IV certification to that patent. *Teva* slip op. The court reviewed the delisting provision, section 505(j)(5)(D)(i)(I)(bb)(CC). The Agency had applied this provision in previous adjudications such that delisting of the patent for any reason by the NDA holder could result in forfeiture. Teva had asserted that FDA's interpretation of the delisting provision, although applied by FDA only in adjudications involving other drugs and different parties, was both subject to immediate review by the court and not supported by the statute.[3] The court, in a 2-1 decision, agreed with Teva on both grounds, and ruled that Merck's delisting of the '075 patent could not be the basis for forfeiture of exclusivity by the first applicant for generic Cozaar and Hyzaar. Slip op. at 29.

The D.C. Circuit, in response to a request from Teva, issued the mandate on an expedited basis on

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[3] On July 31, 2009, the U.S. District Court for the District of Columbia found that it had jurisdiction to review the matter, but granted judgment in favor of the government on the merits. *Teva Pharms. USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42 (D.D.C. 2009).

March 12, 2010, and remanded the case to the district court.[4] On March 26, 2010, the district court amended an order it had issued on March 16, 2010, to clarify that Teva has not forfeited its 180-day exclusivity under the Failure to Market provision, section 505(j)(5)(D)(i)(I). The district court stated that forfeiture due to patent expiration under section 505(j)(5)(D)(i)(VI) was not raised in Teva's Complaint and was not addressed by the D.C. Circuit in either its March 2, 2010 Opinion or in the March 12, 2010 issuance of the mandate. The district court ordered FDA to file a notice of its decision on the '075 patent expiration issue by 5 p.m. on March 26, 2010.

Expiration of the '075 Patent

When Teva first raised the question of 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar before the district court in June 2009, FDA's records showed a March 4, 2014 expiration date for the '075 patent, and no outside party had brought any other expiration date for the patent to the Agency's attention. It was only after the March 2, 2010 *Teva* decision that FDA was notified by Apotex that the Patent and Trademark Office records showed that the '075 patent had expired for failure to pay fees. Now that Merck has confirmed to FDA that the '075 patent expired on March 4, 2009, FDA is addressing whether the patent expiration is a separate basis, apart from the delisting, for forfeiture

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[4] The Solicitor General is considering seeking rehearing of the Court of Appeals' decision. If rehearing is sought by the government and granted, the mandate would be recalled.

of exclusivity.[5] To obtain comment from interested parties on the effect of the revised patent expiration date, FDA sent a letter to ANDA applicants on March 11, 2010, and opened a public docket for submission of comments (FDA-2010-N-0134).

FDA has considered these submissions, as well as the relevant statutory provisions, regulations, and case law, in developing the views described in this response.[6]

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[5] In *Teva*, the government argued that the court should not address the dispute concerning 180-day exclusivity being pressed by plaintiff Teva until FDA had decided that issue. One basis for the government's position was the potential that factual and/or legal issues specific to the circumstances associated with the Teva claim would require an FDA analysis that would, at a minimum, be useful to the court in its decision-making. The court rejected that position. FDA believes that the new and complicated issues raised by the expiration of the patent at issue in this case provide a good example of why courts should await an agency decision in a particular matter rather than anticipate an agency's decision based on previous rulings in similar matters.

[6] Due to the limited amount of time remaining before April 6, 2010, when one or more ANDAs referencing Cozaar and Hyzaar are expected to be eligible for final approval, FDA initiated its request for comment on the effect of a March 4, 2009 expiration date for the '075 patent before it had received the confirmation from Merck of the correct expiration date. Further, because of the exceptional circumstances of this case, FDA is making a decision on 180-day exclusivity before April 6, 2010. Because of the possibility that relevant facts will change, it is FDA's usual practice to wait until at least one ANDA is otherwise eligible for final approval before the Agency makes decisions regarding 180-day exclusivity. Among other considerations underlying FDA's decision to address the patent expiration at this time is the *Teva*

Neither the district court nor the D.C. Circuit addressed the effect of the expiration of the '075 patent on the first applicant's eligibility for 180-day exclusivity, nor could they have done so because, as noted, when the courts ruled, neither they nor FDA was aware of the fact that the '075 patent had expired. Therefore, FDA is addressing the matter here. First, the Agency analyzes the issue as if it were writing on a clean slate, and interpreting and applying the statute without reference to the recent *Teva* decision. Second, the Agency describes the effect of the Court of Appeals' reasoning in the *Teva* delisting decision on the outcome in this particular patent expiration matter.

Merck, the NDA holder, has notified FDA that the sole patent giving rise to a claim of 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar, the '075 patent, has expired. The patent information provided to FDA by the NDA holder controls for patent certification purposes. *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) ("FDA operates in a purely ministerial role, relying on NDA holders to provide the Agency with accurate patent information."). Therefore, in assessing the first applicant's claim to exclusivity, FDA will rely on Merck's statement that the '075 patent has expired.

The effect of a patent expiration on exclusivity is specifically addressed in the 180-day exclusivity

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court's decision on 180-day exclusivity based on events involving the same patent at issue in the current matter.

provisions applicable to the ANDAs referencing Cozaar and Hyzaar. Section 505(j)(5)(B)(iv) of the Act, as amended by the MMA, states:

> Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

"Subparagraph (D)" describes how a first applicant will forfeit its 180-day exclusivity period upon the occurrence of different types of a "forfeiture event" with respect to that applicant. Section 505(j)(5)(D). Among the defined events resulting in forfeiture is "Expiration of All Patents," which occurs when "[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired." Section 505(j)(5)(D)(i)(VI). If this forfeiture event applies to a first applicant, the applicant forfeits exclusivity immediately upon the expiration of all patents as to which it qualified as a first applicant.[7] If there is only

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[7] The forfeiture events described in sections 505(j)(5)(D)(i)(II)-(V) are similarly immediate in effect if they are found to apply to a first applicant. It is interesting to note the contrast between these "immediate" forfeiture events, which provide no

one patent that serves as a basis for 180-day exclusivity, when that patent expires, there will be no exclusivity for the drug product, and the Agency may approve any otherwise approvable ANDA.

Under FDA's longstanding interpretation, once a patent expires, eligibility for 180-day exclusivity based on that patent is extinguished. This is true

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opportunity for the first applicant to use its exclusivity period once the forfeiture event has occurred, and the "Failure to Market" forfeiture event described in 505(j)(5)(D)(i)(I), which provides that upon the occurrence of certain events, rather than face immediate forfeiture, the first applicant will have the opportunity to begin commercial marketing of the drug product and thus start the running of its 180-day exclusivity period. For each of the events set out in 505(j)(5)(D)(i)(I)(bb), the first applicant has 75 days from the date of the specified event to begin marketing and receive the benefits of exclusivity. These provisions describe events that could occur with respect to "the first applicant *or any other applicant*" (emphasis added), as well as the patent deli sting provision interpreted by the court in *Teva*. Presumably, Congress structured this exclusivity forfeiture provision so that, even if it is an applicant other than a first applicant that triggers a forfeiture by, for example, obtaining a final decision of non-infringement, the first applicant will nevertheless have a limited opportunity to benefit from being the first to challenge the patent. It is reasonable for FDA to conclude that, once at least one applicant has obtained a final court decision or settlement stating that the patent at issue is invalid or not infringed–or the patent has been delisted by the NDA holder because it does not meet the patent listing requirements–Congress sought to balance the benefits derived from the exclusivity incentive against the delay in the availability of generic drugs resulting from that exclusivity, and thus established a limit on the length of time during which the exclusivity would be available. In the case of patent expiration, Congress concluded that not even a limited 180-day exclusivity barrier to approval was warranted once the patent expired.

under both the pre-MMA 180-day exclusivity provisions and the MMA exclusivity provisions applicable to the ANDAs referencing Cozaar and Hyzaar. The pre-MMA exclusivity provisions did not explicitly address whether 180-day exclusivity could survive the expiration of the patent. In addressing that statutory gap, FDA stated that once a patent expires, the correct certification to the patent is a "paragraph II" certification pursuant to section 505(j)(2)(A)(vii)(II)("that such patent has expired"). Once the application no longer contains a paragraph IV certification to the patent, the applicant no longer has a basis to obtain exclusivity as to that patent. This was held to be a reasonable interpretation of the pre-MMA exclusivity provision. *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 356-57 (D.N.J. 2003). Moreover, even when the D.C. Circuit found in *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006), that the pre-MMA exclusivity provisions would not permit an NDA holder's delisting of a patent to defeat a first applicant's claim on exclusivity, the court noted that "as Ranbaxy and Teva acknowledged at oral argument, the text and the structure of the [pre-MMA] statute suggest a distinction between expiration and delisting such that the first generic applicant may no longer retain exclusivity when the patent has expired." *Id.* at 126 n.3 (citing, inter alia, *Dr. Reddy's Labs.*). The forfeiture provision at section 505(j)(5)(D)(i)(VI), enacted in the MMA, thus embodies the familiar principle that 180-day exclusivity does not survive patent expiration.[8]

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[8] The MMA did not revise the descriptions of patent

The issue presented by the expiration of the '075 patent is not whether, as a general rule, exclusivity will be forfeited pursuant to section 505(j)(5)(D)(i)(VI) upon the expiration of a patent, but whether a patent expiration for failure to pay fees is an exception to this rule.[9] The Agency's view is that, if it were writing on a clean slate, it would interpret the statute so that patent expiration for any reason is a patent expiration forfeiture event. FDA believes that interpretation is most consistent with the plain meaning of the words of the statute and with a workable and appropriate approach to administration of the statute.

The text of the patent expiration forfeiture event provision does not provide a basis to distinguish between "natural patent expiry" and expiration for some other reason.[10] Section 505(j)(5)(D)(i)(VI) refers broadly to forfeiture when "all of the patents...have expired." There is no language qualifying the type of expiration the Agency is to consider relevant for

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certifications set forth at section 505(j)(2)(A)(vii).

[9] Teva, for example. appears to acknowledge that forfeiture will occur upon "natural patent expiry." March 18, 2010 Comment from Teva at 3.

[10] Teva's comment does not define "natural patent expiry." For example, that term presumably could encompass both the expiration of the original 17 or 20 year term of a patent and the expiration of the term of certain patent claims that have been extended under 35 U.S.C. § 156. FDA's requirements do not limit the type of patent expiration information that may be submitted to FDA. 21 C.F.R. § 314.53.

forfeiture.[11] Thus, there is no apparent statutory basis for the Agency to conclude that only some patent expirations result in forfeiture.

Some of the comments noted a number of reasons why FDA should create an exception to patent expiration forfeiture when the patent expires because the patent owner has failed to pay applicable fees. Among these are concerns about the lack of certainty regarding the expiration when the patent expires due to non-payment of fees. The March 18, 2010 comments from Teva and from Olsson, Frank & Weeda (OFW) identify situations in which a patent that has expired can be "revived" through payment by the patent owner of fees. Teva comment at 2-3; OFW comment at 3-4, 9-10.

Although it may well be the case that a patent that has expired for failure to pay fees could, in certain circumstances, be revived, this possibility alone is an inadequate basis to maintain that a later expiration date must control. As an initial matter, FDA will not change the applicable patent expiration date unless the NDA holder tells the Agency to do so. If the NDA holder (who is also likely to be the patent owner or licensee) notifies FDA that the patent has expired due to failure to pay fees, it can be presumed

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[11] Based on the lengthy list of patents that expired on March 4, 2009, that was submitted as Attachment B to the March 9, 2010 Apotex letter raising the '075 patent expiration issue, expiration for failure to pay fees is not uncommon. Nonetheless, FDA is not aware of any other case in which it has been notified by an NDA holder that a patent that had been submitted to FDA and listed in the Orange Book has expired due to non-payment of fees.

to have resolved at least to a reasonable certainty the finality of the patent expiration. Further, the concerns about uncertainty of expiration would presumably extend to all situations in which a patent has expired due to failure to pay fees, including those in which, although 180-day exclusivity is not an issue, reliance on a later expiration date could delay generic drug approvals. For example, if an NDA holder notified FDA that a patent on a drug as to which no ANDA had yet been submitted had expired due to failure to pay fees, but FDA refused to accept the NDA holder's representation because of uncertainty that the patent would remain "expired," future ANDA applicants would be required to submit patent certifications for a patent that may have its natural patent expiration years in the future. If the NDA holder is sufficiently certain its patent has expired that it notifies FDA of that fact, FDA believes that generic drug applicants are entitled to rely on that patent expiration date in seeking approval for their drug products.

Finally, in assessing what expiration date should control for purposes of 180-day exclusivity, it is appropriate for FDA to continue to rely on the NDA holder's representations to FDA. *Teva v. Leavitt*, 548 F.3d at 106. In this case, for example, although Apotex brought the question of the correct expiration date for the '075 patent to FDA's attention, the Agency did not consider the patent expiration date to be March 4, 2009 (and publish that date in the Orange Book) until Merck notified FDA that March 4, 2009 was the correct date. Had Merck maintained that the patent expiration date remained March 4,

2014, FDA would have retained the March 4, 2014 date in its records and relied on that date for patent certification, exclusivity, and application approval purposes. As stated in FDA's regulations,

> Unless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list [the Orange Book]. If the new drug application holder does not change the patent information submitted to FDA, ... an abbreviated new drug application under section 505(j) of the act submitted for a drug that is claimed by a patent for which information has been submitted must, despite any disagreement as to the correctness of the patent information, contain an appropriate certification for each listed patent.

21 C.F.R. § 314.53(f). Even though information on patent expirations due to failure to pay fees is available from the PTO, it would not be an appropriate use of FDA resources for FDA to forgo its ministerial role in these matters and make its own assessments of patent expiration. In light of the commenters' concerns about the uncertain nature of these patent expirations, it would seem particularly important that the Agency continue to defer to the NDA holder's judgment regarding the expiration of its patent.

The expiration of a patent is a specific basis for forfeiture of exclusivity under the MMA, and it also necessitates a change in the ANDA applicants' patent certifications. The MMA patent certification provisions, like the pre-MMA provisions, state that the appropriate certification to an expired patent is a "paragraph II" (that such patent has expired). Section 505(j)(2)(A)(vii)(II). Upon expiration of a patent, a paragraph IV certification to the patent automatically becomes invalid. *Ranbaxy Labs Ltd. v. FDA*, 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished). Thus, a paragraph IV certification to the expired '075 patent is invalid, and the appropriate certification to the patent is "paragraph II." The 180-day exclusivity provision at section 505(j)(5)(B)(iv) directs that FDA determine whether an ANDA "contains a [paragraph IV] certification ... and is for a drug for which a first applicant has submitted an application containing such a certification." When a first applicant's ANDA does not contain a valid paragraph IV certification or a non-first applicant's ANDA no longer contains a paragraph IV certification, the 180-day exclusivity provision at section 505(j)(5)(B)(iv), by its own terms, does not apply.[12] Thus, permitting the first applicant to retain exclusivity as to an expired patent requires FDA to take an action that is not sanctioned by the words of the statute.

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[12] The MMA also defines a "first applicant" eligible for exclusivity as an applicant that, among other things "submits a substantially complete application that contains *and lawfully maintains* [a paragraph IV certification]." Section 505(j)(5)(B)(iv)(II)(bb) (emphasis added). An applicant cannot lawfully maintain a paragraph IV certification to a patent that has expired.

For the reasons described above, FDA concludes that if it were assessing this issue without reference to the *Teva* decision, it would find that, under the plain language of the statute, because the '075 patent will have expired by the time any ANDA referencing Cozaar or Hyzaar is ready for approval, any first applicant previously eligible for 180-day exclusivity as to the '075 patent forfeits that exclusivity. Moreover, even if the statutory language is considered ambiguous, FDA concludes loss of exclusivity under these circumstances is most consistent with the statute's text and goals, and provides the most reasonable way of administering the statute.

Effect of *Teva* Decision on Patent Expiration Forfeiture

FDA does not believe it can assess the effect of expiration of the '075 patent due to nonpayment of fees on exclusivity for generic Cozaar and Hyzaar without consideration of the D.C. Circuit's *Teva* decision and the reasoning in that decision regarding the delisting of the '075 patent.

In *Teva*, the D.C. Circuit concluded that Teva is entitled to exclusivity, in spite of the fact that the NDA holder has requested delisting of the patent, based on the "structure" of the statute, regardless of the words of the statute.[13] Moreover, the court

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[13] The D.C. Circuit specifically stated:

> We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able

concluded that this analysis was appropriately considered under "*Chevron* step one," *i.e.*, that there was no statutory ambiguity that FDA is free to resolve based on its understanding of the statute and the industry it regulates. Slip op. at 29. After rejecting Teva's "linguistic" argument, slip op. at 24, the court adopted a "structural argument" based on the pre-MMA *Ranbaxy* case. Slip op. at 24. It found that the structure of the MMA exclusivity provisions, as with the pre-MMA exclusivity provision considered in *Ranbaxy*, does not permit an NDA holder to "unilaterally" deprive the generic applicant of its exclusivity on the basis of delisting.[14] Slip op. at 5, 29.

> to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve. For that reason, the interpretation of the statute that the FDA has adopted in two recent adjudications, and that it regards itself as bound by law to apply to Teva's ANDAs for losartan products, fails at Chevron step one.

Slip op. at 29.

[14] The *Teva* court's decision suggests that it believed the statute would permit innovator companies to delist patents at will to deprive the first applicant of exclusivity, i.e., that "Brand manufacturers are ... free to delist challenged patents whenever they please ...." Slip op. at 24, 25. Patent listing is not optional. In fact, NDA holders are required by statute to provide patent information to FDA if, but only if, the patent claims the drug product or an approved use of the product, and if "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Section 505(b)(1). Thus, the patent holder may not simply withdraw or change patent information previously submitted to FDA because of some desire to interfere with the 180-day exclusivity of a potential generic competitor. It is, of course, true that FDA does not have the patent expertise to

This reasoning thus appears to preclude a forfeiture of exclusivity on the basis of a patent expiration where the expiration is in the control of the NDA holder. Because the '075 patent expired due to Merck's failure to pay applicable fees, that expiration, consistent with the Court of Appeals' reasoning in *Teva*, is not a grounds for forfeiture of the first applicant's exclusivity. Although FDA believes this result is inconsistent with the plain language of the statute, as discussed above, lit believes it is appropriate to apply the Court of Appeals' reasoning to the present facts. In the event the D.C. Circuit reconsiders and revises the decision in *Teva*, FDA reserves the right to revisit these conclusions regarding 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar.

FDA thus finds that, consistent with the reasoning of the Court of Appeals, despite having been delisted by the patent owner and having expired, the '075 patent nevertheless must be considered to remain a basis for 180-day exclusivity.

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enforce the statutory requirement that appropriate patents be listed or delisted. Because the continued listing of an inappropriate patent, with the resulting blocking of competition, can place the NDA holder in jeopardy of antitrust damages, considerations of antitrust liability may well be factors in innovator decisions to withdraw patent information previously submitted. In fact, settlement of disputes between innovator companies and the Federal Trade Commission can result in patent delistings. *See, e.g.*, Report, *In the Matter of Bristol-Myers Squibb Co.*, Docket No. C-4076 (Federal Trade Comm'n, June 20, 2003) (describing delisting of patents for Serzone, Buspar, and Taxol) The *Teva* decision could affect the availability and effectiveness of delisting as a remedy.

FDA will not approve any other ANDA referencing Cozaar or Hyzaar until the first applicant has received approval of its ANDA, begun commercial marketing, and the 180-day exclusivity period has expired.[15] The Agency makes this finding even though it is not the result that FDA, as the agency that administers the statute, believes is appropriate given the relevant statutory language or the policies underlying the statute.

Conclusion

For the reasons described above, the Agency has concluded that, in light of the D.C. Circuit's decision in *Teva*, the March 4, 2009 expiration of the '075 patent for failure to pay applicable fees does not result in forfeiture of the first applicant's 180-day exclusivity for ANDAs referencing Cozaar and Hyzaar. If you have any questions regarding this decision, please contact Dave Read, Regulatory Counsel, Office of Generic Drugs at (240) 276-9310.

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[15] We note that even though the *Teva* litigation has proceeded on the assumption that a first applicant will receive approval and begin marketing promptly after all applicable patent and exclusivity barriers expire, the rule derived from this case would presumably apply even if the first applicant did not promptly obtain approval and begin to market, *e.g.*, because of changes in the application that required additional review, unsatisfactory inspections, or unavailability of materials. In such cases, FDA could be barred from approving otherwise approvable subsequent ANDAs until either the first applicant eventually triggered its exclusivity with commercial marketing and the 180-day period expired, or the delisted patent expired "naturally," with the result that competition from lower priced generic drugs would be delayed.

Sincerely,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

[March 26, 2010]

APPENDIX D

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued Dec. 7, 2009 Decided March 2, 2010
No. 09-5281

TEVA PHARMACEUTICALS USA, INC.,
APPELLANT
v.
KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY OF HEALTH & HUMAN SERVICES, ET AL.,
APPELLEES

Consolidated with 09-5308

Appeals from the United States District Court for the District of Columbia,
(No. 1:09-cv-01111-RMC)

Michael D. Shumsky argued the cause for appellant. With him on the briefs were *Jay P. Lefkowitz* and *Gregory L. Skidmore*.

Carmen M. Shepard and *Kate C. Beardsley* were on the briefs for cross-appellant Apotex, Inc. in No. 09-5308.

Drake Cutini, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Eugene M. Thirolf Jr.*, Director, David S. Cade, Acting General Counsel, United States Food

and Drug Administration, *Michael M. Landa,* Acting Associate General Counsel, and *Eric M. Blumberg,* Deputy Chief Counsel.

Carmen M. Shepard and *Kate C. Beardsley* were on the brief for *amicus curiae* Apotex, Inc. in support of appellees.

Before: HENDERSON and GRIFFITH, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* WILLIAMS.

Dissenting opinion filed by *Circuit Judge* HENDERSON.

WILLIAMS, *Senior Circuit Judge*: This is the latest installment in a long-running series of cases concerning an incentive that Congress established for companies to bring "generic" versions of branded drugs to market faster than they otherwise might. Teva Pharmaceuticals USA, Inc., a manufacturer of generics, has received tentative approval from the U.S. Food and Drug Administration to sell losartan potassium products—used primarily to treat hypertension. The approval will become final once the "pediatric exclusivity period"[1] ends, following the expiration of the last remaining patent on Merck's pioneered versions of the same drugs, sold under the names Cozaar and Hyzaar. When that date arrives

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[1] This is a six-month extension of the time during which all generic competition against a branded drug is prohibited, see 21 U.S.C. § 355a; it is not a subject of dispute here.

(April 6, 2010), Teva believes that it should be entitled to the six-month period of marketing exclusivity that generic drug makers earn, in some circumstances, for successfully taking the risks and bearing the costs of showing the invalidity or inefficacy of a patent that a brand-name drug maker has said blocks competing products. See *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060, 1063-65 (D.C. Cir. 1998) (describing the incentive regime established by the Hatch-Waxman Act of 1984); *Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120, 121-22 (D.C. Cir. 2006).

Thwarting its receipt of that entitlement, however, is an FDA interpretation of the operative statutory regime (the Food, Drug, and Cosmetic Act, as amended by various other laws, codified in relevant part at 21 U.S.C. § 355) that will allow not only Teva but all generic manufacturers to sell their approved losartan potassium products right out of the gate. In short, Teva says that, effective April 6, 2010, the agency's interpretation will deprive the company of the competitive advantage Congress has said it should enjoy.

To ward off this danger, Teva filed suit in the federal district court for the District of Columbia in June 2009, seeking a declaration that the relevant FDA policy is unlawful and an injunction compelling the agency to act in accordance with Teva's reading of the statute. Despite protestations by the government that the matter was not ripe for review and that Teva lacked standing, the district court reached the merits of the claim—but ruled in the FDA's favor. *Teva*

Pharmaceuticals U.S.A, Inc. v. Sebelius, 638 F.Supp.2d 42 (D.D.C. 2009). Teva now appeals that decision. We agree that the suit is justiciable, and hold that the FDA's interpretation is inconsistent with, and thus foreclosed by, the statutory scheme.

* * *

In the process of obtaining FDA approval to sell a pioneering new drug, an applicant lists publicly all of the patents that, it believes, would be infringed by "bioequivalent" versions of the product sold by other companies. *Ranbaxy*, 469 F.3d at 121-22 (discussing 21 U.S.C. § 355(a)-(b)(1)). Prospective generic competitors need not, however, take these lists as gospel. After a new drug hits the market, they can effectively challenge the brand maker's pronouncement by filing a certification that a proposed generic version of the brand drug would not run afoul of one (or more) of the putatively blocking patents, either because the patent is invalid or because the generic maker has found a way to design around it. See *id.* at 122 (discussing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). The generic producer's filing, called a "paragraph IV certification" in our past cases, comes in the course of the generic's own application for FDA approval, known as an Abbreviated New Drug Application, or ANDA. See *id.* (discussing 21 U.S.C. § 355(j)(2)).

Filing a paragraph IV certification comes with a risk, though: it constitutes an act of patent infringement, 35 U.S.C. § 271(e)(2)(A), with the hazard of sparking costly litigation. In order, then, to "compensate [generic] manufacturers for research

and development costs as well as the risk of litigation from patent holders," *Teva Pharmaceuticals USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008), the statute provides that the first company to file an ANDA containing a paragraph IV certification earns an "exclusivity" period of 180 days, during which the FDA may not approve for sale any competing generic version of the drug at issue, *id.* (discussing 21 U.S.C. § 355(j)(5)(B)(iv)). This promise of initial marketing exclusivity is thus intended to increase competition by expediting the availability of generic equivalents. See *id.*; *Serono Laboratories, Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998).

A potential bug in the system is the ability of the brand manufacturer, after a generic has filed a paragraph IV certification, to announce that in fact the challenged patent is not one that protects the drug at issue and to ask the FDA to "delist" the patent, thus purporting to pull the rug from under the paragraph IV certification. In *Ranbaxy* we considered "whether the FDA may delist a patent upon the request of the [brand manufacturer] after a generic manufacturer has filed an ANDA containing a paragraph IV certification so that the effect of delisting is to deprive the applicant of a period of marketing exclusivity." 469 F.3d at 125. The answer, we said, was no; an FDA policy that allowed brand manufacturers to strategically delist challenged patents, thereby unilaterally stripping generic manufacturers of marketing exclusivity, was "inconsistent with the structure of the statute." *Id.*

Ranbaxy, however, interpreted the law as it stood before Congress amended it in 2003 via the Medicare Prescription Drug, Improvement, and Modernization Act, Pub.L. No. 108-173, 117 Stat. 2066. *Id.* at 122 n. *. Three times since the effective date of the amendments, the same series of events at issue in *Ranbaxy* has arisen—once involving the generic manufacturer Cobalt Pharmaceuticals and the brand drug Precose, made by Bayer; once involving the generic manufacturer Hi-Tech Pharmacal Co. and the brand drug COSOPT, made by Merck; and now involving Teva, the drugs Cozaar and Hyzaar, and Merck. In the first two instances, the generic makers presented arguments to the FDA why they should still, in the modified statutory regime, be entitled to exclusivity notwithstanding the brand companies' delisting a challenged patent. Teva itself responded to the FDA's solicitation of comments in the Cobalt matter, advocating the same pro-exclusivity reading of the amended statute's treatment of post-paragraph-IV-filing delisting requests. See Letter from Marc Goshko, Executive Director, Teva North America, In Response to FDA Request for Comments re Generic Drug Applications for Acarbose Tablets (Oct. 16, 2007), in Joint Appendix ("J.A.") 78 et seq. In both cases, the FDA ruled that the 2003 amendments required a different outcome from the one *Ranbaxy* ordered under the old version of the law.

The agency pointed to the 2003 amendments' addition of a critical new term to the statute: the "forfeiture event." See 21 U.S.C. § 355(j)(5)(D)(ii). On the occurrence of any one of six defined scenarios, the

law now says, the entitlement to a 180-day exclusivity period "shall be forfeited by a first applicant." See *id.* In both the Cobalt and Hi-Tech disputes, the FDA decided that the facts at issue, paralleling those in *Ranbaxy* and our case, had satisfied the terms of the first listed forfeiture event, "failure to market," and in each case denied the generic manufacturer exclusivity.

The statutory definition of the first listed forfeiture event is as follows:

> (I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—
>
> (aa) the earlier of the date that is—
>
> (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
>
> (BB) 30 months after the date of submission of the application of the first applicant; or
>
> (bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least

1 of the following has occurred:

> (AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.
>
> (BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.
>
> (CC) *The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.*

21 U.S.C. § 355(j)(5)(D)(i)(I) (emphasis added).

The FDA stated its view of the matter in terms echoing the so-called "first prong" of *Chevron, U.S.A. Inc. v. NRDC*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984), see, e.g., *Mova*, 140 F.3d at 1067, explaining: "The effect of patent delisting on eligibility for 180-day exclusivity is expressly

addressed by the [preceding] plain language." Dorzolamide Hydrochloride-Timolo Maleate Ophthalmic Solution-180-day generic drug exclusivity, Dear ANDA Applicant Letter (Oct. 28, 2008) ("Hi-Tech Letter") at 14 n. 15., J.A. 121 n. 15. A company otherwise entitled to exclusivity always forfeits it, said the agency, if events occur satisfying both paragraphs (aa) and (bb). *Id.* Paragraph (aa) gets checked off, thanks to its subsection (BB), as soon as 30 months have passed since the generic maker filed its ANDA—which had long since happened in both Cobalt's and Hi-Tech's cases. And paragraph (bb) is taken care of 75 days after the brand manufacturer delists the challenged patent (under subsection (CC)), regardless of the purpose or circumstance of the delisting request. *Id.* In the later of the two letter rulings, the FDA wrote that it had "considered and rejected in both this case and in the matter described in the [Cobalt] Decision, the argument that eligibility for 180-day exclusivity following the [brand maker's] voluntary withdrawal of its patent should be governed not by the [new] forfeiture provisions, but by the rule established in *Ranbaxy*." Hi-Tech Letter at 14, J.A. 121. Even though neither Cobalt nor Hi-Tech could have sold its generic drug before the date that the FDA said amounted to a "failure to market" event (since unchallenged patents protected the relevant brand drugs until a good deal later), the agency announced that both companies had forfeited exclusivity. Both Cobalt and Hi-Tech sought judicial review, were denied relief in district court, and didn't appeal.

Teva filed the ANDAs at issue in this case on December 18, 2003, for Cozaar, and May 24, 2004, for Hyzaar. Both contained a paragraph IV certification targeting Merck's U.S. patent No. 5,608,075, which does not expire until 2014, and left unchallenged Merck's other, earlier-expiring patents on the drugs. In response to Teva's filing, Merck chose not to sue for infringement, as it might have. Instead, on March 18, 2005, Merck asked the FDA to delist the 075 patent, which the agency did, though without making the action public until April 18, 2008. Appellees' Br. at 17. As of the present date, the FDA has awarded tentative approval to Teva's ANDAs, see *Teva,* 638 F.Supp.2d at 58 n. 12, and also to an ANDA filed by a competitor of Teva's, Apotex Inc., to sell generic Hyzaar, see Reply Br. at 11 n. 9. Though the FDA does not formally announce which ANDA filer was the first to submit a paragraph IV certification with respect to a brand drug (or whether any generic manufacturer is officially entitled to exclusivity) until the date on which generic sales can actually begin, see 21 C.F.R. § 314.430(b), Teva has every reason to believe that it was the first filer for both drugs at issue here: it points to the fact that the FDA's own website lists the first paragraph IV certification against Hyzaar (i.e., "Losartan Potassium and Hydrochlorothiazide") as having been filed on the very day that Teva filed its own Hyzaar ANDA. See http:// www. fda. gov (enter "Hyzaar ANDA" in search box; select sole result, "[PDF] Paragraph IV Patent Certifications"; scroll to page 16) (last visited December 21, 2009).

But in light of the Hi-Tech Letter, Teva saw the writing on the wall: under the interpretation of the "plain language" of the amended statute that the FDA had twice adopted, Teva had by the fall of 2008 *already* forfeited the exclusivity it believed it had earned—on August 12, 2006 for the generic Cozaar ANDA, and on January 16, 2007 for the generic Hyzaar ANDA.[2] Moreover, the agency had twice rejected the contention, made once by Teva itself as a commenter, that its chosen interpretation of the statute was untenable for a number of reasons, among them that it was inconsistent with *Ranbaxy*. Eschewing presentation of the same argument to the agency for yet a third time, though the first time with its own ANDA directly on the line, Teva went straight to the district court, hoping for a declaratory judgment rejecting the FDA's interpretation and an order that the FDA grant it exclusivity on the date that generic losartan potassium competition would begin, April 6, 2010.

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[2] The calculation under the FDA's understanding of the statute looks like this: With respect to Cozaar, the date satisfying paragraph (aa) of the "Failure to Market" forfeiture event is August 12, 2006 (30 months since the filing of the ANDA, see subsection (BB))—and the date satisfying paragraph (bb) is 75 days after March 18, 2005 (when Merck asked that the drug be delisted, see subsection (CC)); of the two dates, August 12, 2006 is the later one, hence (under the opening clause of § 355(j)(5)(D)(i)(I)) the forfeiture event. With respect to Hyzaar, the analysis is the same, except that 30 months from the date of the ANDA's filing fell on January 16, 2007. See also Hi-Tech Letter at 15 (saying that the subsection (CC) event is calculated from the date of the brand maker's delisting request, not the date that FDA makes public the delisting).

* * *

The posture of this case raises several significant questions about its justiciability. One concerns conventional ripeness. A second, an issue of standing, implicates a potential—though ultimately illusory—conflict between, on one hand, decisions of this court regarding a plaintiff's ability to obtain pre-enforcement review of a policy adopted by an agency in an adjudication and, on the other hand, the well-established teaching of *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992), that the imminent threat of injury inflicted by the defendant and redressable by the court suffices for constitutional standing.

Ripeness

Pre-enforcement judicial review of an agency's policy is available only if the dispute is ripe. *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 123 S.Ct. 2026, 155 L.Ed.2d 1017 (2003). The ripeness inquiry probes the fitness for review of the legal issue presented, along with (in at least some cases) "the hardship to the parties of withholding court consideration." *Id.* at 808, 123 S.Ct. 2026. The "fitness" prong of the analysis generally addresses "whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *National Ass'n of Home Builders v. U.S. Army Corps of Engineers*, 440 F.3d 459, 463 (D.C. Cir. 2006).

In this case, the substantive issues Teva raises are undoubtedly "purely legal" in the relevant sense. They turn on questions of statutory construction, see *Shays v. FEC*, 414 F.3d 76, 95 (D.C. Cir. 2005), and the interpretations chosen by the FDA and proposed by Teva both constitute bright-line rules, impervious, so far as appears, to factual variation. This in itself largely answers the question whether delay might afford additional "concrete[ness]"; it would not. As to finality, that largely resolves into the questions whether the FDA actually has a policy, whether it's clear what will happen when the FDA applies the policy to Teva, and whether in any event it's sufficiently likely that the policy will matter at all, given possible uncertainty whether Teva would be entitled to exclusivity even if the agency's take on 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (CC) matched Teva's.

While the FDA could in principle change its position as to the effect on generics' exclusivity of brand makers' requests to delist, an about-face seems extraordinarily unlikely. In its brief, the agency maintains, as it did in the Cobalt matter and the Hi-Tech matter, that the interpretation it adopted in those instances is *compelled* by the statute and that arguments to the contrary are plainly futile. Appellees' Br. at 42-43 ("[T]he plain language of subsection (CC) makes clear that the provision applies *whenever* a patent is withdrawn by the [patent holder.]" (emphasis in original)). The mere theoretical possibility that an agency could alter its views on a legal issue before enforcing them against a party has not, in the past, precluded pre-enforcement review of those views. The same possibility exists for

rulemakings, as we observed in *Association of Bituminous Contractors, Inc. v. Andrus*, 581 F.2d 853, 859 (D.C. Cir. 1978), and for less finely chiseled agency decisions, see *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000). As in *Appalachian Power,* there is here virtually no doubt, as a practical matter, what approach the agency will apply to Teva. And the implication of the FDA's position for any exclusivity that Teva would otherwise merit is equally clear: as discussed above, the unambiguous result of the agency's interpretation is that any such entitlement is already forfeited.

The government argues, however—relying chiefly on *Pfizer Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999)—that the issue nevertheless remains unfit for review because the agency's challenged interpretation may not be dispositive of the question whether Teva ultimately deserves exclusivity. In *Pfizer* a brand manufacturer (Pfizer) filed suit alleging that the FDA's mere acceptance of an ANDA for processing was unlawful because the proposed generic drug differed in a crucial respect from the product it sought to replicate. 182 F.3d at 978. We found the suit unripe, suggesting that despite the FDA's tentative approval of the generic's ANDA, grounds for uncertainty over whether the generic drug would ever be approved for sale persisted, posing concerns for "piecemeal litigation": we instanced a possible FDA finding of a lack of bioequivalence, a matter that we obviously assumed the tentative approval left open. *Id.* at 980.

The absence of any colorable factual dispute in Teva's case compels a different outcome from *Pfizer*. The FDA makes no suggestion that any possible deficiency or uncertainty in Teva's ANDA could thwart final approval. It offers no reason to doubt the conclusion that the first paragraph IV certification against Hyzaar, filed on May 24, 2004, was the paragraph IV certification against Hyzaar that Teva filed on May 24, 2004—which in turn dictates that Teva has satisfied the threshold requirement for exclusivity. The agency does caution that one or more of the statutory "forfeiture events" other than a "failure to market" might in any case deprive Teva of exclusivity before final approval–but as Teva's counsel ably demonstrated at oral argument, any such outcome is virtually inconceivable: Teva will not withdraw its ANDA, see 21 U.S.C. § 355(j)(5)(D)(i)(II); it will not amend its paragraph IV certification, see § (D)(i)(III); it has already obtained tentative approval, see § (D)(i)(IV); there is no indication that it will enter a collusive agreement with Merck, see § (D)(i)(V); and the now-delisted patent will not expire, see § (D)(i)(VI). See Oral Argument Tr. at 29-30 (Dec. 7, 2009). In short, the question before us is one of pure statutory interpretation; we know precisely what the FDA thinks the answer is; and its resolution will almost certainly determine whether Teva is entitled to the exclusivity it claims.

The second prong of the ripeness analysis addresses "whether *postponing* judicial review would impose an undue burden on" the parties. *National Ass'n of Home Builders*, 440 F.3d at 464 (emphasis in

original). This court has frequently suggested that hardship is not a *sine qua non* of ripeness. See *id.* at 465 ("[W]here ... there are no significant agency or judicial interests militating in favor of delay, [lack of] hardship cannot tip the balance against judicial review." (second bracketed alteration in original, internal quotation marks omitted)); *Electric Power Supply Ass'n v. FERC*, 391 F.3d 1255, 1263 (D.C. Cir. 2004) ("The hardship prong under the ripeness doctrine is largely irrelevant in cases ... in which neither the agency nor the court have [*sic*] a significant interest in postponing review."); *AT & T Corp. v. FCC*, 349 F.3d 692, 700 (D.C. Cir. 2003) ("The 'hardship' prong of the *Abbott Laboratories* [*v. Gardner*, 387 U.S. 136, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967)] test is not an independent requirement divorced from the consideration of the institutional interests of the court and agency. Thus, where there are no institutional interests favoring postponement of review, a petitioner need not satisfy the hardship prong." (internal citation omitted)); *Village of Bensenville v. FAA*, 376 F.3d 1114, 1120 (D.C. Cir. 2004) ("[A]lthough the FAA reasonably asserts that the municipalities will not 'suffer [any] immediate hardship from an EIS,' Respondent's Br. at 23, we see no benefit to us in *postponing* review[.]" (emphasis and second bracketed alteration in original)). In this case we need not consider the effect of a failure to show hardship, as Teva faces at least one harm from delayed judicial review cognizable in the ripeness analysis: a near-certain loss of the first-mover advantage to which the company claims entitlement.[3]

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[3] Teva also alleges hardship resulting from the severe impact of

If Teva is right on the merits (as we must assume it is for purposes of the ripeness inquiry, see *U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1014 (D.C. Cir. 2002)), then as of April 6, 2010, it will be entitled to start enjoying its exclusivity period and to continue doing so for 180 days before additional firms lawfully enter the market. This "first-mover advantage" is a valuable asset. In *Mova* we observed "the loss of [a generic's] officially sanctioned head start" can, at least in some circumstances, yield a "severe economic impact." 140 F.3d at 1066 n. 6 (internal quotation marks omitted). If we refrained from adjudicating this dispute now, Teva would almost certainly face competition from Apotex on April 6, see 21 C.F.R.

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uncertainty on investment decisions that it must make well before the first legal opportunity to sell its generic, whether as an exclusive (as it claims) or not (under the FDA's view). Delayed resolution of the issues in this case will, depending on the assumptions under which it operates, either (1) cost the company much of a valuable (and lawful) commercial opportunity, if it mistakenly assumes that the FDA view will prevail and therefore refrains from investing sufficient resources to prepare for the increased demand that would accompany an exclusive as opposed to a non-exclusive product launch, or (2) waste hundreds of millions in company resources invested in anticipation of fully exploiting its exclusivity, if it mistakenly assumes that its view will prevail. See Declaration of David Marshall, Vice President of New Products Portfolio Strategy for Teva Pharmaceuticals USA, Inc., at 4-8, J.A. 128-32. (Of course a straddling investment decision would entail some of each cost.) We express no view as to whether such harm counts in the ripeness analysis. Cf. *Exxon Mobil Corp. v. FERC*, 501 F.3d 204, 208 (D.C. Cir. 2007) (hardship ample where postponing review would cause uncertainty and cost to *prospective* applicant for approval to build pipeline and would "tend to inhibit or delay investment" in a project Congress had deemed important).

§ 314.105(d) (explaining that a "tentative" approval is the same as a final approval with a delayed effective date)—an injury that would not be remedied by Teva's securing 180 days of exclusivity later on.

District courts in this circuit routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue. See, e.g., *Teva*, 548 F.3d 103 (earliest possible date of generic competition June 29, 2008, see Appellee's Br. at 5; district court decision April 11, 2008, *id.* at 4); *Ranbaxy*, 469 F.3d 120 (earliest possible date of generic competition June 23, 2006, see Appellants' Br. at 11; district court decision April 30, 2006, *id.* at 1). This makes good sense; the exclusivity reward that Congress made available as an incentive for patent challenges is time-sensitive, and where there is no material ambiguity about essential facts a court can readily decide whether it has been earned in advance of generic competition's onset. The alternative approach—delaying review until the agency has made its technically tentative decisions final—puts a court in an awkward bind, unless it miraculously manages to resolve the merits issue more or less instantaneously. Apart from that risky and improbable course, there would be two possible stopgaps available to preserve the first-mover advantage. The court could delay *all* generic competition, thereby thwarting the statutory purpose of achieving swift competition by generics (a factor that would in turn weigh against preliminary injunctive relief under the "public interest" component of the standard test). Or it could delay the

entrance of the exclusivity claimant's generic rivals into the market, thereby giving the claimant precisely the relief it seeks, simply in order to allow the court time to decide whether such relief was warranted. The technical possibility that a judge might embrace one of these highly imperfect alternatives can hardly be thought to protect Teva from the hardship made likely by delayed review.

When the question at issue is well-defined, and when withholding judicial consideration would cause undeniable harm, as here, ripeness concerns pose no obstacle to pre-enforcement review.

Standing

The FDA embraced the statutory interpretation that Teva now seeks to challenge not in a rulemaking but in two adjudications to which Teva was not a party (though actively commenting in one). Our past cases suggest some uncertainty whether a dispute in that posture can ever be justiciable. See, e.g., *Radiofone, Inc. v. FCC*, 759 F.2d 936, 938 (D.C. Cir. 1985) (opinion of then-Judge Scalia) ("All persons adversely affected by [a] rule ["addressed, so to speak, to the world at large"] would have standing to challenge its compliance with legal prescriptions designed for their protection....The situation is different, however, when an interpretation of a statute, or some other legal principle, is set forth *as the rationale of an adjudication*." (emphasis in original)).

But straightforward application of hornbook doctrine yields the conclusion that Teva has standing.

Article III of the Constitution requires that a federal court plaintiff allege an actual or imminent injury that is fairly traceable to the defendant's challenged conduct and redressable in the judicial proceeding. *Lujan*, 504 U.S. at 560-61, 112 S.Ct. 2130. In this instance, the latter two elements are clearly satisfied. Any imminent deprivation of Teva's allegedly deserved exclusivity would be directly attributable to the FDA's statutory interpretation. And if we agreed with Teva on the merits, we (or the district court) could issue precisely the declaration it has sought, announcing that requests to delist challenged patents should have no more legal significance in the amended statutory regime than they did in the old one, as per *Ranbaxy*, 469 F.3d at 126.

The "injury" prong of the standard standing inquiry is a bit thornier—but only to the extent of the trivial uncertainty whether the FDA will on April 6, 2010 stick to the interpretation that Teva attacks here. As discussed in the ripeness analysis above, however, we find no uncertainty to speak of on the matter. It is clear what the FDA will do absent judicial intervention and what the effect of the agency's action will be. The inescapable implication is that Teva faces an imminent threat of the same harm that has sufficed for Article-III injury purposes in all of our past drug-approval cases: the impending prospect of allegedly unlawful competition in the relevant market. See, e.g., *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1497 (D.C. Cir. 1996) ("[W]here...a statutory provision reflects a legislative purpose to protect a competitive interest, the protected competitor has standing to require

compliance with that provision."); *Ranbaxy*, 469 F.3d 120 (adjudicating a dispute in which the only injury at issue was the prospective loss of a generic manufacturer's 180-day period of marketing exclusivity). For the purpose of the classic constitutional standing analysis, it makes no difference to the "injury" inquiry whether the agency adopted the policy at issue in an adjudication, a rulemaking, a guidance document, or indeed by ouija board; provided the projected sequence of events is sufficiently certain, the prospective *injury* flows from what the agency is going to do, not how it decided to do it. Cf. *City of Los Angeles v. Lyons*, 461 U.S. 95, 106 n. 7, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983) ("[T]o have a case or controversy ... [plaintiff] would have to credibly allege that he faced a realistic threat from the future application of the City's policy.").

The question, then, is whether the normal application of the constitutional standing doctrine is suspended when the court's knowledge that an agency is about to inflict injury on a party derives from an agency policy that originated in an adjudication (or several). The strongest support for such a principle would be *Sea-Land Service, Inc. v. Department of Transportation*, 137 F.3d 640, 648 (D.C. Cir. 1998), in which we rejected a pre-enforcement challenge to an agency interpretation born of an adjudication, noting that a policy's "mere precedential effect within an agency is not, alone, enough to create Article III standing, no matter how foreseeable the future litigation" involving the plaintiff. We have articulated a similar idea, albeit in weaker form, on numerous other occasions. See, e.g.,

Shipbuilders Council of America v. United States, 868 F.2d 452, 456 (D.C. Cir. 1989) ("[W]e know of no authority recognizing that the mere potential precedential effect of an agency action affords a bystander to that action a basis for complaint."); *American Family Life Assurance Co. v. FCC*, 129 F.3d 625, 629 (D.C. Cir. 1997) ("*AFLAC*") ("[W]e have said before, and we say again, that the 'mere precedential effect of [an] agency's rationale in later adjudications' is not an injury sufficient to confer standing on someone seeking judicial review of the agency's ruling." (quoting *Radiofone*, 759 F.2d at 939)).

In all of these cases, we rebuffed efforts to obtain pre-enforcement review of policies embraced by agencies in adjudications. In each instance, however, the failure to demonstrate standing is more naturally understood as arising from the lack of a sufficiently imminent and concrete injury than from some sort of ad hoc exception to otherwise-universally applicable constitutional doctrine. *Radiofone*, for example, addressed whether parties allegedly aggrieved by reasoning employed by the FCC in an adjudication could appeal the agency's order even though the recipient of the order had since ceased doing business. 759 F.2d at 937-38. There was no suggestion in any of the panel's three opinions—including then-Judge Scalia's, which didn't in any case garner a majority for its standing passage—that the parties seeking review were at risk of injury from imminent application of the principle the agency had articulated. *Shipbuilders* similarly concerned no identifiable prospective application of the allegedly

offending policy. We explicitly noted, in fact, that plaintiffs had failed to present "specific, concrete facts demonstrating that the challenged [ruling would] harm" them, adding that their "hypothesizing ... never descends from a highly general plane; it remains at a considerable distance from the more concrete pleas" needed to establish standing. *Shipbuilders*, 868 F.2d at 457. While the opinion also framed the complaint as an impermissible "request for judicial advice—a declaration that a line of agency rulings should henceforth have no precedential effect," *id.* at 456, we simply did not address the scenario in which a line of agency rulings threatened a party with an imminent injury otherwise ample for Article III purposes.

Sea-Land, too, did not involve a party pointing to a particular imminent application of the disputed agency policy. The justiciability problem in that case arose from the "principle that prevailing parties lack standing to appeal," 137 F.3d at 647—which is undoubtedly correct as a general matter, but which does not foreclose review of a case in which a party is aggrieved not by the "mere potential precedential effect of an agency action," *Shipbuilders*, 868 F.2d at 456, but instead by the impending *application* of an agency's statutory interpretation, the firmness of which is not in dispute, on a fast-arriving date certain. The *Sea-Land* opinion, to be sure, phrased the proscription against challenges to agency precedent *qua* precedent as one applying "no matter how foreseeable the future litigation." 137 F.3d at 648. But we could not possibly have purported to overturn well-established Supreme Court precedent

holding that an *imminent* threat of injury suffices for standing, see *Lujan*, 504 U.S. at 560, 112 S.Ct. 2130-particularly in a case not involving the slightest allegation of such a threat. A more sensible reading of *Sea-Land* is one that leaves it consistent with *Lujan* and its equally binding progeny: merely foreseeable future litigation resulting from a statutory interpretation that an agency has adopted in an adjudication is, "alone," 137 F.3d at 648—i.e., without more—too speculative to satisfy Article III's injury-in-fact requirement. An agency's imminent application of its established interpretation of a statute, at the potential cost of hundreds of millions of dollars to the regulated firm, remains, by contrast, as sufficient for standing purposes today as it was before *Sea-Land*. See Marshall Declaration at 4-5, J.A. 128-29 (explaining why Teva "stands to lose hundreds of millions of dollars in net revenues during its first year of generic losartan potassium products sales as a direct result of the [FDA's policy]").

No other case we've decided concerning a pre-enforcement challenge to an agency interpretation adopted via adjudication counsels a contrary result. See *AFLAC*, 129 F.3d at 628 ("Petitioner reports no litigation on the horizon ... no simmering disputes about to erupt into a lawsuit[.]"); *Shell Oil Co. v. FERC*, 47 F.3d 1186, 1202 (D.C. Cir. 1995) ("Shell's allegations of injury rest on a hypothetical scenario.... Although such injury is not inconceivable, we are unpersuaded that it is *imminent*." (emphasis in original)); *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 674 (D.C. Cir. 1994) (finding impact of agency's challenged position on party seeking review

"nebulous and remote"); *Aeronautical Radio, Inc. v. FCC*, 983 F.2d 275, 284 (D.C. Cir. 1993) ("There is no indication in the record ... that the Commission is likely to attempt to [enforce the challenged interpretation against TRW, the party seeking review]. TRW's alleged injury is therefore merely conjectural." (internal quotation marks omitted)).

We have, on the other hand, allowed a party to challenge in advance an agency policy adopted via adjudication when the prospect of impending harm *was* effectively certain. In *International Brotherhood of Electrical Workers v. ICC*, 862 F.2d 330 (D.C. Cir. 1988), a union sought judicial review of the Interstate Commerce Commission's exercise of jurisdiction to review an arbitration award—even though the ICC, having accepted jurisdiction, had ruled *in favor of* the union. 862 F.2d at 334. We found ripeness and standing requirements satisfied, noting that "[b]ecause of the ICC's decision to review arbitration awards, the union will be subject to agency review in future cases involving disputes" of the same type. *Id.* As we later explained, *International Brotherhood* stands for the proposition that the "concrete cost of an additional proceeding is a cognizable Article III injury," *Sea-Land*, 137 F.3d at 648—notwithstanding that the source of the harm was an agency position adopted in an adjudication whose outcome was no longer at issue. Teva's alleged injury threatens to impose no less of a "concrete cost" and with no less certainty.

We have, moreover, explicitly sanctioned review of a case in the present posture—albeit while framing

the justiciability question as one of ripeness rather than standing. *Association of Bituminous Contractors v. Andrus*, 581 F.2d 853, 858-59 (D.C. Cir. 1978), was precisely a pre-enforcement challenge to a policy adopted in a previous adjudication by the Interior Board of Mine Operations Appeals. The doctrine of standing has undoubtedly evolved significantly since the time of that decision (though not generating any new limits on imminent injuries that happen to be traceable to adjudicative rules)—but the case does demonstrate that we have previously considered the lawfulness of an agency policy with precisely the kind of provenance as the policy Teva challenges, where imminent application of the policy was about to inflict injury. See also *Independent Insurance Agents of America, Inc. v. Hawke*, 211 F.3d 638 (D.C. Cir. 2000) (adjudicating dispute over agency interpretation adopted in letter ruling to which district court plaintiff was not party); *Air Transport Ass'n of America, Inc. v. FAA*, 291 F.3d 49 (D.C. Cir. 2002) (same, where dispute concerned letter ruling to which circuit court petitioner was not party).

We see no basis for concluding that this court has created an exception to the Supreme Court's constitutional standing doctrine excising cases like Teva's from the class of otherwise justiciable matters. Teva presents a valid Article III case or controversy.

* * *

On the merits, we review de novo the district court's grant of summary judgment to the FDA. See *Kersey v. Washington Metropolitan Area Transit Authority*, 586 F.3d 13, 16 (D.C. Cir. 2009). We

evaluate the FDA's interpretations of the Food, Drug, and Cosmetic Act adopted in letter rulings under the familiar two-part *Chevron* framework. *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1280 (D.C. Cir. 2004). But see Matthew C. Stephenson and Adrian Vermeule, Chevron *Has Only One Step*, 95 Va. L.Rev. 597 (2009).

Teva offers two principal reasons to conclude that the FDA may not allow a brand manufacturer's request to delist a challenged patent to trigger a statutory "forfeiture event" resulting in the loss of a generic's exclusivity. One reason takes the form of linguistic analysis focused almost entirely on the text of the "failure to market" forfeiture event and a related provision. The 2003 amendments, Teva explains, introduced a new procedure, a counterclaim in the brand manufacturer's patent infringement suit, through which generic companies can *force* brand companies to delist an improperly asserted patent. See 21 U.S.C. § 355(j)(5)(C)(ii)(I).[4] This counterclaim provision is the only portion of the statute that explicitly provides for the delisting of a patent after it has been challenged in an ANDA. In

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[4] The purpose of this procedure, says Teva, is to offer generics a means of combating brand companies' practice of delaying generic competition by listing "sham patents," baiting a generic into filing a paragraph IV certification, and then filing an infringement suit—which typically brings a 30-month stay of generic competition. Appellant's Br. at 42; see 21 U.S.C. § 355(j)(5)(B)(iii) (creating the stay and subjecting it to various limits such as the generic manufacturer's earlier success in the suit); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 236 (4th Cir. 2002) (describing precisely this delay tactic).

the company's view, that singular reference requires the conclusion that the counterclaim provision describes *the only scenario* in which the FDA may delist a challenged patent. Obviously, then, no other kind of delisting could ever serve as an occurrence satisfying the terms of the "failure to market" forfeiture trigger listed at 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

The FDA, for its part, responds that "the plain language of the statute contains no limitation on when delisting can occur." Appellees' Br. at 44. Brand manufacturers are thus free to delist challenged patents whenever they please—and any such delisting satisfies subsection (CC) of the "failure to market" forfeiture section. *Id.* at 45-46. In effect, the agency says, the *counterclaim* provision says nothing about its being an exclusive route to delisting, and if Congress meant to confine subsection (CC) delistings to those arising from the counterclaim procedure, it would have been natural for it to place that limitation in (CC).

While Teva's purely linguistic argument shows its understanding of the relevant language to be perfectly plausible, it hardly rules out alternative readings that, absent consideration of statutory structure, also appear plausible. See *Chevron*, 467 U.S. at 844-45, 104 S.Ct. 2778; *INS v. Cardoza Fonseca*, 480 U.S. 421, 443, 107 S.Ct. 1207, 94 L.Ed.2d 434 (1987) (considering "the structure of the Act" at *Chevron* step one). As the FDA notes, there is simply no express preclusion of non-counterclaim delistings, or of such delistings' triggering forfeiture,

in either of the places one might expect to find one, the counterclaim section or (CC).

This brings us to Teva's structural argument. *Ranbaxy*, Teva notes, concerned an FDA policy with a virtually identical effect. See 469 F.3d at 125. This court condemned that rule, partly because it allowed a brand manufacturer,

> by delisting its patent, to deprive the generic applicant of a period of marketing exclusivity. By thus reducing the certainty of receiving a period of marketing exclusivity, the FDA's delisting policy diminishe[d] the incentive for a manufacturer of generic drugs to challenge a patent ... in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire. *The FDA may not, however, change the incentive structure adopted by the Congress,* for the agency is bound "not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes."

Id. at 126 (emphasis added, citation omitted). Nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act altered that essential incentive structure, says Teva, so the preceding portion of *Ranbaxy* remains applicable even under the new regime. Indeed, it is true that the 2003 amendments

say nothing specific to undermine our prior understanding of the statute's intended incentive structure.

But the FDA sees a way in which its interpretation of subsection (CC) accomplishes at least some congressional purpose. Without the possibility of a forfeiture of exclusivity resulting from the delisting of a challenged patent, a generic manufacturer that had been awarded exclusivity could delay all generic competition more or less indefinitely, since by statute the agency can't approve competing generics until 180 days after the first paragraph-IV filer has *begun commercial marketing* of its newly approved product. See 21 U.S.C. § 355(j)(5)(B)(iv)(I). Congress enacted the "failure to market" provision, in the agency's view, precisely to avoid such "parking" of exclusivity; allowing a brand maker to trigger forfeiture by delisting a challenged patent positively furthers that legislative aim. Appellees' Br. at 45. Besides, the agency says, "Consumers benefit from lower drug prices immediately without having to wait for one generic company to enjoy 180 days of exclusivity when the patent owner itself takes the position that a patent should not hinder FDA approval of ANDAs." *Id.*

The real issue, then, is whether the FDA is right that the 2003 addition of the "failure to market" forfeiture provision, 21 U.S.C. § 355(j)(5)(D)(i)(I), altered the statute's incentive structure to the point that *Ranbaxy*'s reasoning no longer controls the agency's treatment of a delisting request in the wake of a paragraph-IV filing.

The terms of § 355(j)(5)(D)(i)(I), quoted in full in the opening of this opinion, create five possible dates on which a generic manufacturer otherwise entitled to exclusivity can forfeit it: (1) 75 days after the agency finally approves the relevant ANDA; (2) 30 months after the generic submits the relevant ANDA; (3) 75 days after a court judgment that the challenged patent is invalid or not infringed; (4) 75 days after a suit over the challenged patent is settled favorably to the ANDA filer; and (5) 75 days after the challenged patent is delisted. No forfeiture occurs, however, unless one of dates (1)-(2) *and* one of dates (3)-(5) have come to pass. See *id.*; FDA Letter re 180-day exclusivity, Docket No. 2007N-0389, ANDA 77-165: Granisetron Hydrochloride Injection, 1 mg/mL, at 5, J.A. 68 ("We find that under the plain language of the statute, 180-day exclusivity is not forfeited for failure to market when an event under subpart (aa) has occurred, but ... none of the events in subpart (bb) has occurred."). Setting aside the subsection at issue in this case—listed as (5) above, and codified as (bb)(CC)—the "failure to market" forfeiture provision does not permit a brand manufacturer to vitiate a generic's exclusivity without the generic manufacturer's having had some say in the matter. No forfeiture can take place unless the brand manufacturer brings an infringement suit against the generic and either loses on the merits or enters an unfavorable settlement agreement. The latter necessarily entails some participation by the generic; the former invariably involves significant expense for the brand manufacturer, and affords the victorious generic the opportunity to ask the court to delay entering final judgment until a date that would not

trigger forfeiture prematurely—before the agency grants final approval to the relevant ANDA.

The FDA's view turns the last alternative among events (3)-(5) into a fundamentally different forfeiture trigger: it is satisfied when the patent targeted in a paragraph-IV filing "is withdrawn by the" brand manufacturer, full stop-meaning that Congress has now explicitly provided for a scenario in which the brand maker can unilaterally deprive the generic of its exclusivity. The agency, however, offers *not a single cogent reason* why Congress might have permitted brand manufacturers to trigger subsection (CC) by withdrawing a challenged patent, outside the counterclaim scenario identified by Teva.

The argument that the plain language of the statute imposes no limit on the circumstances in which the agency may effectuate delisting requests fails. Precisely the same could have been said of the version of the statute that *Ranbaxy* addressed, and we nevertheless concluded that its structure precluded an FDA rule allowing the agency "to delist a patent upon the request of the [brand manufacturer]" when the delisting would rob the generic maker of earned exclusivity. 469 F.3d at 125.

The agency fares no better in suggesting that allowing the delisting of challenged patents prevents the ANDA filer from "creat[ing] a bottleneck" blocking generic competition by "parking" its exclusivity. Appellees' Br. at 45. As a parking-prevention device, letting brand makers delist challenged patents in order to trigger a forfeiture of

exclusivity would be completely ineffective; given the incentives for the brand manufacturer, it will be used *only* where its impact on Congress's scheme is most destructive. If the generic appears likely to park its exclusivity, the brand maker will simply refrain from delisting altogether, thus enjoying an extended period during which it faces *no* generic competition while the exclusivity-holder bides its time.[5] If the generic appears unlikely to park its exclusivity, the brand maker can delist well before the generic can go to market, thus eviscerating the exclusivity incentive altogether. In other words, the only case in which a unilateral right for brand makers to delist challenged patents actually results in the outcome the FDA touts is when the brand maker deliberately accelerates the onset of generic competition—an utterly implausible scenario. In other cases, the brand maker either does nothing to prevent parking, or prevents parking that was unlikely to have occurred in any event, but with precisely the effect that *Ranbaxy* proscribed. Thus the "parking" concern offers no reason to conclude that the 2003 addition of forfeiture provisions meant to give the brand manufacturer a right to unilaterally vitiate a generic's exclusivity.

Finally, the FDA's sole effort to root its interpretation in the policy underlying Hatch-Waxman—the thought that the interpretation benefits consumers by allowing full generic

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[5] We note, in fact, that many instances of generics' parking their exclusivity have evidently arisen thanks to agreements with the brand maker itself to delay generic competition. See Federal Trade Commission, Authorized Generics: An Interim Report ch. 2, at 1 (2009).

competition without a 180-day delay—betrays a misunderstanding of the exclusivity incentive. The statute's grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support brand drugs. The statute thus deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted. As Congress deliberately created the 180-day exclusivity bonus, the FDA cannot justify its interpretation by proudly proclaiming that it has eviscerated that bonus.

We see nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act that changes the structure of the statute such that brand companies should be newly able to delist challenged patents, thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise deserve. For that reason, the interpretation of the statute that the FDA has adopted in two recent adjudications, and that it regards itself as bound by law to apply to Teva's ANDAs for losartan products, fails at *Chevron* step one. Cf. *Ranbaxy*, 469 F.3d at 126; *Cardoza-Fonseca*, 480 U.S. at 443, 107 S.Ct. 1207.

* * *

One matter remains. Teva's prospective generic losartan competitor, Apotex, sought to intervene as a defendant in Teva's suit before the district court. The court denied the intervention on the ground that Apotex lacked standing. *Teva*, 638 F.Supp.2d at 59. Apotex has appealed that ruling, but has also, with the consent of both parties, expressed its substantive views of this case in an amicus brief, which we have considered no less than if Apotex had formally intervened. As Apotex and the FDA are as a practical matter identically positioned on the issues (though from radically different perspectives), we think it prudent to follow the line of precedent in this circuit declining to assess a would-be intervenor's standing when answering the question wouldn't affect the outcome of the case. See *Comcast Corp. v. FCC*, 579 F.3d 1, 6 (D.C. Cir. 2009) ("We need not decide whether [the harm alleged by a prospective intervenor] is too 'conjectural or hypothetical' to support standing ... because 'if one party has standing in an action, a court need not reach the issue of the standing of other parties when it makes no difference to the merits of the case.'" (quoting *Railway Labor Executives Ass'n v. United States*, 987 F.2d 806, 810 (D.C. Cir. 1993))); see also *McConnell v. FEC*, 540 U.S. 93, 233, 124 S.Ct. 619, 157 L.Ed.2d 491 (2003) ("It is clear ... that the Federal Election Commission (FEC) has standing, and therefore we need not address the standing of the intervenor-defendants, whose position here is identical to the FEC's."). We note that courts appear not to have considered whether a party whose attempt to intervene has been pretermitted in this fashion (or a party whose

standing has otherwise been left unresolved) can seek review of the court's decision on the merits, as a successful intervenor could. Perhaps courts have assumed that that issue could reasonably be kicked up the road to the possible appellate body. Finally, we also note that Apotex might move again for intervention in future proceedings before the district court in this case in light of changed circumstances—specifically that Apotex's ANDA has now earned tentative approval from the FDA, effectively removing the obstacle to standing on which the district court relied.

* * *

We therefore reverse the judgment of the district court, but, as the court has yet to address the appropriateness of each form of relief that Teva has sought, we remand for further proceedings not inconsistent with this opinion.

So ordered.

KAREN LECRAFT HENDERSON, *Circuit Judge*, dissenting:

I dissent from the majority opinion because the issue Teva seeks to litigate—its statutory eligibility vel non to exclusively market generic versions of Cozaar and Hyzaar, brand name drugs manufactured by Merck & Co., Inc. (Merck)—will not be ripe unless and until the United States Food and Drug Administration (FDA) issues its final decision either granting or denying Teva's Abbreviated New Drug Application (ANDA). The United States Supreme Court has established a two-pronged test for determining ripeness, requiring that the court analyze: "(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808, 123 S.Ct. 2026, 155 L.Ed.2d 1017 (2003) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 149, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967)). This action satisfies neither prong of the ripeness test as is clear from our decision in *Pfizer Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999).

In that case, Pfizer filed a "citizen petition" with the FDA asking that the agency recognize as "a distinct dosage form" a patented "osmotic pump" used as an extended release mechanism for Pfizer's brand drug Procardia XL. *Pfizer*, 182 F.3d at 977. Almost four years later—with the petition still pending—Mylan Pharmaceuticals, Inc. (Mylan) filed an ANDA to market a generic version of Procardia XL, claiming pharmaceutical equivalence notwithstanding Mylan's product used a different release mechanism. After the

FDA accepted Mylan's ANDA for processing but before it decided whether to approve it, Pfizer filed a suit in district court challenging the FDA's acceptance of the ANDA on the ground that the two products were not equivalent because Pfizer's osmotic pump was a unique dosage form and thus distinct from Mylan's mechanism. The district court held that Pfizer's challenge to Mylan's application was not ripe for judicial review but that its unresolved citizen petition was. *Id.* at 978. On appeal, we found neither challenge ripe.

We first rejected Pfizer's argument that "once having decided, based upon the information contained in Mylan's application, that Mylan's drug uses the same dosage form as Procardia XL®, the FDA will not 'alter its views with respect to the necessity of Mylan filing a suitability petition.' " *Id.* at 978. We explained:

> The decision to accept Mylan's ANDA for processing as a pharmaceutical equivalent to Procardia XL® is ... merely the first step in the agency's approval process. The critical fact remains that the FDA may never approve Mylan's application-whether because it decides in the end that the dosage form of Mylan's drug is different from that of Procardia XL® or for some entirely different reason, such as a lack of bioequivalence. Therefore, "depending upon the agency's future actions ... review now may turn out to have been

> unnecessary" and could deprive the agency of the opportunity to apply its expertise and to correct any mistakes it may have made.

Id. (quoting *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 736, 118 S.Ct. 1665, 140 L.Ed.2d 921 (1998)) (first ellipsis added). Teva faces the same hurdle here. We do not know whether the FDA's final decision will approve Teva's ANDA or what the FDA's reasoning will be if, as the majority forecasts, maj. op. at 1308-10, it does not. The FDA may conclude Teva forfeited its eligibility upon Merck's delisting of its patents, as Teva and the majority insist it will, or it may reject Teva's application based on one of the other forfeiture provisions "or for some entirely different reason, such as a lack of bioequivalence." *Pfizer*, 182 F.3d at 978.[1] Because the FDA has not yet issued its decision we are unable to divine its substance. Given this uncertainty and the consequent possibility the court may not need to resolve the delisting/forfeiture issue after the FDA's final decision, Teva's challenge to the FDA's previous decisions in other proceedings is not now fit for review under the first prong of the ripeness test. In short, "[i]t makes no sense for us to anticipate a

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[1] The FDA's "tentative approval" of Teva's ANDA is not, as Teva suggests, Reply Br. at 10-11, the final word on its generic drug's equivalence. See *Pfizer*, 182 F.3d at 980 (although FDA's post-oral argument tentative approval of Mylan's generic made it "more likely that the FDA w[ould] eventually approve Mylan's drug, the agency's tentative approval cause[d] Pfizer no hardship at present or in the near future, nor d[id] it render Pfizer's challenge fit for review").

wrong when none may ever arise." *Cronin v. FAA*, 73 F.3d 1126, 1132 (D.C. Cir. 1996).

Nor does Teva fare better under the test's hardship prong as we applied it in *Pfizer*. There we explained that Pfizer was not able to "point to any imminent hardship arising from the FDA's acceptance of Mylan's ANDA":

> Before Pfizer could suffer its claimed "economic injury from unlawful competition," FDA approval for a pharmaceutical equivalent to Procardia XL® would have to be not only sought but granted. That has not happened. Therefore "no irremediable adverse consequences flow from requiring a later challenge."

Pfizer, 182 F.3d at 979 (quoting *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 164, 87 S.Ct. 1520, 18 L.Ed.2d 697 (1967)). For the same reason, Teva too will suffer no *imminent* hardship if review is postponed. *See Fed. Express Corp. v. Mineta*, 373 F.3d 112, 119 (D.C. Cir. 2004) (hardship prong not satisfied because "postponing review ... w[ould] not be a hardship to [petitioners], let alone a hardship that is '*immediate*, direct, and significant.' " (quoting *State Farm Mut. Auto. Ins. Co. v. Dole*, 802 F.2d 474, 480 (D.C. Cir. 1986))) (emphasis added). As in *Pfizer*, the delay will not "foreclose [the appellant's] right ever to get meaningful judicial *review*," 182 F.3d at 979; upon the FDA's issuance of an adverse final order, Teva is free to seek judicial review—forestalling generic

competition and the loss of the "first-mover advantage," maj. op. at 1311, through appropriate and immediate injunctive relief.[2]

For the foregoing reasons, I would find the appeal is unripe and dismiss it for lack of jurisdiction.[3]

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[2] And contrary to my colleagues' lack of confidence in judicial alacrity, maj. op. at 1311, courts make speedy decisions on injunction applications in ANDA cases all the time. See, e.g., *Apotex, Inc. v. FDA*, C.A. No. 06-627, 2006 WL 1030151 (D.D.C. Apr. 19 2006); *Biovail Corp. v. FDA*, C.A. No. 06-1487 (D.D.C. Aug. 25, 2006); *Merck & Co. v. FDA*, 148 F.Supp.2d 27 (D.D.C. June 2001).

[3] In support of ripeness, the majority asserts: "District courts routinely reach the merits of generic manufacturers' claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue." Maj. op. at 1311 (citing *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103 (D.C. Cir. 2008); *Ranbaxy Labs., Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006)). Leaving aside what effect a court's routine practice may have on an issue's ripeness vel non, I know of no instance where the district court reached the merits of an ANDA before the FDA has issued *any decision* regarding the plaintiff and the issue raised. In the two cases the majority cites, the district court directly reviewed FDA decisions denying relief to the plaintiffs. *See Teva Pharms.*, 548 F.3d at 105 (reviewing denial of citizen petition contesting FDA's delisting of patent certified in its ANDA); *Ranbaxy Labs., Ltd.*, 469 F.3d at 121 (reviewing denial of citizen petition denial). Here, by contrast, the FDA has taken no adverse action whatsoever regarding the effect of delisting on Teva's ANDA—and apparently will not do so unless and until it denies final approval. Had Teva raised the delisting issue before the FDA in the first instance, its status here might be different.

APPENDIX E

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA
PHARMACEUTICALS
USA, INC.,

Plaintiff,

v.

Civil Action
No. 09-1111 (RMC)

KATHLEEN SEBELIUS,
Secretary of Health and
Human Services, *et al.*,

Defendants.

MEMORANDUM OPINION

Teva Pharmaceuticals USA, Inc. ("Teva"), a manufacturer of generic drugs, seeks a preliminary injunction to invalidate a "Delisting Rule" instituted by the Food and Drug Administration ("FDA"). The FDA contends that there is no such "Delisting Rule." Instead, in informal adjudications regarding other drugs, the FDA has held that a name brand manufacturer's withdrawal of a patent as a basis for its drug(s) (*i.e.*, a request that the patent be "delisted") triggers a forfeiture provision excising the generic company's eligibility for a 180-day exclusive marketing period. Teva contends that by way of these decisions the FDA has created a "rule" that is subject

to challenge. The FDA moves to dismiss, arguing that its decisions do not constitute a final rule subject to challenge and that, because there has been no final agency action on Teva's own request for generic drug approval, the matter is not ripe and Teva lacks standing. The Court held oral argument on July 13, 2009, and now decides that the FDA's motion to dismiss will be denied. Further, the preliminary injunction proceedings are combined with trial on the merits and judgment will be granted in favor of the FDA. The FDA's statutory interpretation is not arbitrary or capricious.

I. BACKGROUND FACTS

A. Statutory Scheme

The Drug and Price Competition and Patent Term Restoration Act of 1983 (the "Hatch-Waxman Amendments"),[1] 21 U.S.C. § 355 & 35 U.S.C. §§ 156, 271, & 282, established a streamlined procedure for FDA approval of generic drugs. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998). The original applicant for approval of a drug (the "Innovator") must file a New Drug Application ("NDA"), including data from studies showing the drug's safety and effectiveness. *Id.*; *see also* 21 U.S.C. § 355(a) & (b). The Innovator also is required to submit information on any patent that claims the drug or a method of using the drug for which patent infringement could be asserted against an unauthorized party. 21 U.S.C. § 355(b)(1) & (c)(2).

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[1] The Hatch-Waxman Amendments amended the Food, Drug & Cosmetic Act, 21 U.S.C. §301 *et seq.*

The FDA lists such patent information in a publication called the "Approved Drug Products with Therapeutic Evaluations," commonly known as the "Orange Book." *Id.*; 21 C.F.R. § 314.53(e).

Subsequent applicants who want to manufacture generic versions of the Innovator's drug may file an Abbreviated New Drug Application ("ANDA"). *Mova*, 140 F.3d at 1063; 21 U.S.C. § 355(j). The ANDA is not required to include new safety and effectiveness data, but instead may rely on the safety and effectiveness data in the original filing. 21 U.S.C. § 355(j). In this way, the Hatch-Waxman Amendments were intended both to encourage innovative new drugs and to permit the marketing of lower cost generic drugs quickly. *Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 139 (3d Cir. 1987).

An ANDA applicant must certify whether the generic drug would infringe any existing patents relied on and listed by the Innovator. The applicant may certify:

> (I) that the required patent has not been filed;
>
> (II) that the patent has expired;
>
> (III) that the patent has not expired, but will expire on a particular date; or
>
> (IV) that the patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii).[2] A paragraph III certification means that the ANDA applicant does not intend to market the drug until after the patent expires; approval of the ANDA may be made effective on the expiration date. *Id.* § 355(j)(5)(B)(ii). A paragraph IV certification contemplates that the ANDA applicant challenges the validity of the patent or claims that the patent would not be infringed by the generic product proposed in the ANDA. An applicant must provide notice of a paragraph IV certification to the Innovator. *Id.* § 355(j)(2)(B). The filing of a paragraph IV certification constitutes an act of infringement under patent law, 35 U.S.C. § 271(e)(2)(A), and the Innovator, as patent holder, has 45 days to bring suit against the ANDA applicant. *Id.* § 355(j)(5)(B)(iii). If the Innovator brings such a suit, the FDA must delay approving the ANDA for 30 months. *Id.* This provision, known as the 30-month stay, gives the Innovator time to assert its patent rights before the generic competitor is permitted to enter the market. *Mova*, 140 F.3d at 1064. If the Innovator does not bring suit within 45 days, the FDA may approve a paragraph IV ANDA, and the approval may be effective immediately despite the unexpired patent, provided that other conditions have been met. *Id.*; 21 C.F.R. § 314.107(f)(2).

Under certain circumstances, the statute provides a 180-day exclusive marketing period vis-a-vis other ANDA applicants to the first applicant who files an ANDA with a paragraph IV certification. 21 U.S.C.

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[2] Paragraph I and II certifications are not relevant to this case.

§ 355(j)(5)(B)(iv). That is, the first patent-challenging generic applicant may be awarded a six-month period during which that applicant is the only company allowed to sell a generic version of the name brand drug. Thus, the statute may reward the first generic manufacturer that exposes itself to the risk of patent litigation. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005); *Mova*, 140 F.3d at 1064.

Congress amended 21 U.S.C. § 355(j) in 2003 to add the exclusivity provisions raised by Teva in this case. *See* 21 U.S.C. § 355(j)(5)(D) (part of the Medicare Modernization Act of 2003) (the "MMA"); *see* The Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003).[3] The MMA contains certain "forfeiture provisions" setting forth the conditions under which an ANDA applicant may lose eligibility for the 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(D)(i) & (ii). The forfeiture provision at issue in this case is the one that provides that a first ANDA filer will forfeit exclusivity if it fails to market the drug by a certain date:

> (I) Failure to Market. The first [ANDA] applicant fails to market the drug by the later of-
>
> (aa) the earlier of the date that is-
>
> (AA) 75 days after the date on which the approval of the application of the first

[3] The parties agree that the MMA applies to the ANDAs filed by Teva, as they were filed after the MMA was enacted.

applicant is made effective under subparagraph (b)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), *the date that is 75 days after the date as of which*, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters final judgment that includes a finding that the patent is invalid or not infringed.

(CC) *The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved*

> *under subsection (b) of this section* [i.e., the Innovator].

Id. § 355(j)(5)(D)(i)(I) (emphasis added to highlight provision at issue here). Forfeiture occurs only when the "later" of the events in (aa) or (bb) occurs.

The FDA has twice applied the subsection (bb)(CC) forfeiture provision in public letter decisions, after providing notice and comment. For example, with regard to an ANDA for the drug acrabose, the FDA applied the failure to market forfeiture provision under (bb)(CC), finding that this subsection requires marketing within 75 days from when the patent information is withdrawn by the Innovator. Compl. Ex. 5, Letter from Gary Buehler, Director, Office of Generic Drugs, at 7-9 (May 7, 2008), FDA Dkt. No. 2007-N-0445 ("Acrabose Decision"). The FDA announced its interpretation of subsection (bb)(CC) in broadly applicable terms-"Therefore, FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply *whenever* a patent is withdrawn (or requested to be 'delisted') by the NDA holder." *Id.* at 8 (emphasis added). Likewise, with regard to an ANDA for generic Cosopt, the FDA again explained its interpretation of subsection (bb)(CC) of the MMA-that this subsection applies "whenever" a patent is withdrawn by the Innovator. Compl. Ex. 9, Letter from Gary Buehler, Director, Office of Generic Drugs, at 14 n.15 (Oct. 28, 2008), FDA Dkt. No. 2008-N-0483 ("Cosopt Decision").[4]

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[4] The FDA has determined that the 75 day period runs from the date that the FDA receives the patent holder's request to remove the patent from the Orange Book, even though this date

B. Facts of This Case

The facts of this case are not in dispute. Merck & Co., Inc. ("Merck") is the name brand manufacturer that holds approved NDA No. 20-386 for losartan potassium ("losartan") tablets (sold under the name "Cozaar") and NDA No. 20-0387 for losartan potassium hydrochlorothiazide ("losartan HCTZ") tablets (sold under the name "Hyzaar"). Cozaar and Hyzaar are primarily used to treat hypertension. During the twelve month period that ended March 31, 2009, pharmacists in the United States filled over fifteen million prescriptions for Cozaar and Hyzaar, dispensing 848 million tablets, which amounts to nearly $1.5 billion in sales. Pl.'s Mot. for Prelim. Inj. [Dkt. # 5], Ex. A, Decl. of David Marshall ("Marshall Decl.") ¶ 4.

Merck provided patent information to the FDA for listing in the Orange Book: (1) U.S. Patent No. 5,138,069 ("the '069 patent"); (2) U.S. Patent No. 5,153,197 ("the '197 patent"); and (3) U.S. Patent No. 5,608,075 ("the '075 patent").[5]

Teva filed an ANDA to market generic losartan on December 18, 2003, and an ANDA for generic losartan HCTZ on May 24, 2004. The ANDAs

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generally does not become public until the FDA publishes the request to delist in the Orange Book. Acrabose Decision at 7 n.13; Cosopt Decision at 7.

[5] Merck also provided information regarding another patent regarding the method of use of Cozaar. This patent is not relevant here because Teva does not seek approval for this method of use.

contained paragraph III certifications to the '069 patent and the '197 patent and a paragraph IV certification to the '075 patent. Teva sent a notice of its paragraph IV certification to Merck, but Merck did not sue Teva for infringement within 45 days. Instead, on March 18, 2005, Merck withdrew its reliance on the '075 patent by requesting that the FDA remove it from the Orange Book. Merck holds an additional six-month pediatric exclusivity on the '069 and '197 patents. *See* 21 U.S.C. § 355a(b) (pediatric exclusivity prevents the FDA from approving generic applications for six months after the patent expires). Thus, the '069 patent expires on August 11, 2009, and Merck's pediatric exclusivity with regard to this patent expires February 11, 2010; the '197 patent expires on October 6, 2009, and Merck's pediatric exclusivity expires April 6, 2010. Accordingly, the FDA is barred from approving any ANDAs until April 6, 2010, the date that Merck's pediatric exclusivity on the '197 patent expires.

Under the FDA's interpretation of the law, the time calculations under the failure-to-market forfeiture provision quoted above are not in dispute. Under that provision, an ANDA first-filer loses its eligibility by failing to market its generic drug by the later of two dates. One of the dates is calculated under subsection (aa)—the earlier of the date that is 75 days after the ANDA approval (there is no such date here, as Teva's ANDA has not been approved) or 30 months after the ANDA was submitted (June 19, 2006 for Teva's generic version of Cozaar and November 25, 2006 for Teva's generic version of Hyzaar). In other words, the "earlier" date under

subsection (aa) is June 19, 2006 for Teva's Cozaar ANDA and November 25, 2006 for Teva's Hyzaar ANDA.

The second date is calculated under subsection (bb). Because Merck did not file suit against Teva, the first two events under subsections (bb)(AA) and (BB) which relate to litigation do not apply. Under subsection (bb)(CC), Merck withdrew the patent information on the '075 patent on January 1, 2009. According to the FDA, because Teva did not market its generic drugs within 75 days after January 1, 2009, Teva forfeited exclusivity.[6] The FDA's Acrabose Decision and Cosopt Decision make it clear that the FDA applies the forfeiture provision set forth in (bb)(CC) this way.

Teva brought this suit asking the Court to set aside the FDA's new "Delisting Rule," as reflected in the FDA's Acrabose and Cosopt Decisions. The FDA moves to dismiss for lack of jurisdiction and failure to state a claim. Teva seeks a preliminary injunction and requests that the Court combine the hearing on the preliminary injunction with trial on the merits. *See* Fed. R. Civ. P. 65(a)(2) (a court may advance the trial on the merits and consolidate it with the hearing on preliminary injunction). The FDA did not object to a combined proceeding. Because the issue presented

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[6] This is so even though Teva was barred from bringing its drugs to market because Merck's pediatric exclusivity with regard to the '069 and '197 patents has not expired Teva's right to exclusivity was based only on the '075 patent; if Teva had challenged the '069 and '197 patents, the withdrawal of the '075 patent would not have effectuated a forfeiture.

here is purely a matter of law, the preliminary injunction motion and trial on the merits are consolidated.

II. LEGAL STANDARDS

The FDA moves to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that Teva does not challenge a final agency action and that Teva did not exhaust its administrative remedies. A Rule 12(b)(6) motion challenges the adequacy of a complaint on its face, testing whether a plaintiff has properly stated a claim. A complaint must be sufficient "to give a defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted). Although a complaint does not need detailed factual allegations, a plaintiff's obligation to provide the grounds for his entitlement to relief "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* Federal Rule of Civil Procedure 8(a), which requires that a complaint contain a short and plain statement of the claim showing that the pleader is entitled to relief, requires a "showing" and not just a blanket assertion of a right to relief. *Id.* at n. 3. A court must treat the complaint's factual allegations as true, "even if doubtful in fact," *id.* at 1965, and must draw all reasonable inferences in the plaintiff's favor. *Macharia v. United States*, 334 F.3d 61, 64, 67 (D.C. Cir. 2003).

While the FDA does not explicitly move to dismiss for lack of jurisdiction under Federal Rule of Civil Procedure 12(b)(1), it impliedly seeks a Rule 12(b)(1) dismissal as well by arguing that Teva's claim is not ripe and that Teva lacks standing. On a motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject matter jurisdiction. *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 182-83 (1936); *Evans v. B.F. Perkins Co.*, 166 F.3d 642, 647 (4th Cir. 1999). To determine whether it has jurisdiction, a court may consider materials outside the pleadings. *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

III. ANALYSIS

A. Final Agency Action

The FDA contends that Teva has not stated a claim because Teva does not complain of any final agency action. The FDA will not render any decision regarding Teva's ANDAs until April 2010, and the FDA "intends to make a decision regarding 180-day exclusivity when an ANDA for losartan becomes ready for final approval." Def.'s Mot. to Dismiss [Dkt. # 9] at 18. The FDA reasons that the Acrabose and Cosopt Decisions are FDA decisions regarding whether other ANDAs were eligible for the 180-day exclusivity and do not constitute any decision regarding whether Teva's ANDAs for losartan and losartan HCTZ are eligible for the 180-day marketing exclusivity period. The FDA asserts that what Teva really wants is a determination now regarding

whether it will be entitled to exclusivity if and when the FDA approves its ANDAs in the future. The FDA points out that when another generic manufacturer sought advance approval in *Hi-Tech Pharmacal Co., Inc. v. FDA*, 587 F. Supp. 2d 1 (D.D.C. 2008), the court held that the manufacturer was not entitled to advance approval of marketing exclusivity. In that case, a generic manufacturer (Hi-Tech) brought suit against the FDA, seeking a finding by the FDA that Hi-Tech was entitled to the 180-day marketing exclusivity period and seeking an injunction to prevent the FDA from granting final approval to any other generic drug producer while Hi-Tech enjoyed its marketing exclusivity. The court held that the manufacturer was not entitled to review until there was final agency action. 587 F. Supp. 2d at 8. In addition, the court in *Hi-Tech* determined that the FDA was not required to approve Hi-Tech's request for exclusivity by a time certain, and the FDA's failure to act with respect to the issue of exclusivity did not constitute final agency action. *Id.* at 9-10.

Because the FDA misconstrues Teva's claim, this case is not analogous to *Hi-Tech*. Teva does not seek an advance determination on its request for exclusivity as Hi-Tech did. Teva challenges the FDA's interpretation of the MMA as arbitrary, capricious, and an abuse of discretion in violation of section 706 of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. *See* Compl. ¶ 68. The FDA has interpreted the MMA forfeiture provision (bb)(CC) as applying "*whenever*" an Innovator withdraws a patent. See Acrabose Decision at 8. In the Cosopt Decision, the FDA felt bound by its Acrabose Decision

and applied the same statutory construction. Cosopt Decision at 14 n.15. The statutory interpretation was not reliant on any particular factual circumstance presented by those cases; it was entirely based on the language of the statute. The FDA interpreted the MMA to authorize exclusivity-divesting patent delistings effectuated by a name brand manufacturer's voluntary request.

The APA provides a cause of action to a "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." 5 U.S.C. § 702. Review under the APA is limited to "final agency action"[7] for which there is no other adequate remedy in a court. *Id.* § 704; *Heckler v. Chaney*, 470 U.S. 821, 828 (1985) (a person adversely affected by final agency action is entitled to judicial review so long as no statute precludes review and the action is not committed to agency discretion by law). "Whether there has been 'agency action' or 'final agency action' within the meaning of the APA are threshold questions; if these requirements are not met, the action is not reviewable." *Fund for Animals, Inc. v. Bureau of Land Mgmt.*, 460 F.3d 13, 18 (D.C. Cir. 2006).

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[7] A final agency action "(1) marks the consummation of the agency's decision making process—it must not be of a merely tentative or interlocutory nature; and (2) the action must be one by which rights or obligations have been determined or from which legal consequences will flow." *Domestic Secs., Inc. v. SEC*, 333 F.3d. 239, 246 (D.C. Cir. 2003) (internal quotation marks omitted.)

An "agency action" is "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof." 5 U.S.C. § 551(13). A "rule" is "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4). Thus, the term "final agency action" includes an agency's interpretation of a statute. *UAW v. Brock,* 783 F.2d 237, 248 (D.C. Cir. 1986). "[W]hen a legal challenge focuses on an announcement of a substantive statutory interpretation, courts are emphatically qualified to decide whether an agency has acted outside the bounds of reason." *Id.* at 245. Further, an agency's statement of policy is reviewable whether it is set forth in a formal regulation or is articulated in another context, such as a letter ruling. *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676-77 (D.C. Cir. 1994). An agency may establish binding policy through rulemaking procedures or through adjudications which constitute binding precedent. *Brock*, 783 F.2d at 248.[8] An agency's interpretation of its own governing statute is final agency action fit for judicial review. *Id.* Accordingly, the FDA's interpretation of the MMA in the context of the Acrabose and Cosopt Decisions constitutes a rule of decision made through adjudication, and the FDA's interpretation of the MMA constitutes "final agency action" that is subject to review under APA §§ 702

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[8] The FDA argues that the Acrabose and Cosopt Decisions constituted informal adjudication, not rulemaking. For the purpose of this decision, the distinction makes no difference. Both final rues and final orders are reviewable. 5 U.S.C. §706. Further, binding policy, whether created by rulemaking or adjudication, is reviewable. *Brock*, 783 F.2d at 248.

and 704. Thus, Teva has stated a claim under the APA seeking to set aside the FDA's statutory interpretation as arbitrary and capricious under § 706(2).

B. Exhaustion

The FDA also contends that this case should be dismissed for failure to state a claim due to failure to exhaust administrative remedies. FDA regulations require that, before filing suit in court, a party requesting that the FDA take or refrain from taking an action must first use the citizen petition process set forth in 21 C.F.R. § 10.25. 21 C.F.R. § 10.45(b). Exhaustion required by agency regulation, however, is not jurisdictional. *Ass'n of Flight Attendants-CWA v. Chao*, 493 F.3d 155, 158-59 (D.C. Cir. 2007). Courts have the discretion to decline to require exhaustion where a plaintiff would be irreparably harmed by delay, where the agency lacks the power to grant effective relief, or where exhaustion would be futile. *McCarthy v. Madigan*, 503 U.S. 140, 146-49 (1992). Exhaustion is futile when there is a certainty of an adverse decision, *Randolph-Sheppard Vendors v. Weinberger*, 795 F.2d 90, 105 (D.C. Cir. 1986), or when the agency "has evidenced a strong position on the issue together with an unwillingness to reconsider." *James v. HHS*, 824 F.2d 1132, 1137 (D.C. Cir. 1987).

Teva submitted comments in the docket of the Acrabose Decision in which the precise forfeiture issue it now seeks to litigate was raised. The FDA considered and rejected Teva's argument:

> We have considered and rejected the argument made in [Teva's] comments to FDA's docket that eligibility for 180-day exclusivity following the NDA holder's voluntary withdrawal of its patent should be governed not by the MMA forfeiture provisions, but by the rule established in *Ranbaxy Labs., Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006)....These comments argue that the forfeiture event described in section 505(j)(5)(D)(i)(I)(bb)(CC) of the Act applies only if the withdrawal of a patent is pursuant to the process described at section 505(j)(5)(C)(ii) of the Act. Section 505(j)(5)(C)(ii) contemplates that, as a result of a counterclaim by the ANDA applicant in patent infringement litigation, a court may issue an order requiring that patent information be corrected or deleted. Only in that situation, the argument goes, would the withdrawal of patent information trigger the statutory forfeiture provision. We do not find this argument persuasive [and] FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply whenever a patent is withdrawn (or requested to be "delisted") by the NDA holder.

Acrabose Decision at 8. The FDA evidenced its strong position and its unwillingness to reconsider in the Cosopt Decision by stating, "[w]e also have considered and rejected in both this case and in the ... Acrabose Decision, the argument that eligibility for 180-day exclusivity following the NDA holder's voluntary

withdrawal of its patent should be governed not by the MMA forfeiture provisions, but by the rule established in Ranbaxy." Cosopt Decision at 14. The FDA went on to explain, just as it had in the Acrabose Decision, that it reads subsection (bb)(CC) of the MMA to broadly apply whenever an Innovator withdraws a patent and not only when a patent is withdrawn as a result of counterclaim litigation:

> [A]s noted in the Acrabose Decision at pp. 8-9, we also have considered the argument that the forfeiture event described [in subsection (bb)(CC)] applies only if the withdrawal of a patent is pursuant to the process described at section 505(j)(5)(C)(ii) of the Act.... Only in that situation, the argument goes, would the withdrawal of patent information trigger the statutory forfeiture provision.... [T]he scope of the patent delisting forfeiture provision is much broader.... FDA reads the plain language of 505(j)(5)(D)(i)(I)(bb)(CC) to apply whenever a patent is withdrawn (or requested to be "delisted") by the NDA holder.

Id. at 14 n.15. Teva has exhausted its remedies by participating unsuccessfully in the Acrabose litigation and pursuit of administrative remedies would be futile. In these circumstances, the law does not require further administrative exhaustion.

C. Ripeness

Jurisdiction requires that a claim be ripe for decision. Under the Constitution, federal courts are limited to deciding "actual, ongoing controversies."

Honig v. Doe, 484 U.S. 305, 317 (1988). A claim is not ripe for adjudication if it rests upon "'contingent future events that may not occur as anticipated, or indeed may not occur at all.'" *Texas v. United States*, 523 U.S. 296, 300 (1998) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580-81, 105 S.Ct. 3325, 87 L.Ed.2d 409 (1985)). By requiring that claims be ripe before adjudicating them, courts promote judicial economy, avoid becoming entangled in abstract disputes, and ensure a record adequate to support an informed decision when a case is heard. *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967).

To show that a claim is ripe, a plaintiff must demonstrate (1) the fitness of the issues for judicial decision, and (2) the hardship to the parties caused by withholding court consideration. *Nat'l Treasury Employees Union v. Chertoff*, 452 F.3d 839, 854 (D.C. Cir. 2006) (citing *Abbott Labs.*, 387 U.S. at 149). To determine the fitness of an issue for judicial review, a court must look to see "whether the issue is purely legal, whether consideration of the issue would benefit from a more concrete setting, and whether the agency's action is sufficiently final." *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380 (D.C. Cir. 2002) (quoting *Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1204 (D.C. Cir. 1998)). A petition for review that presents a "purely legal question" satisfies the "fitness" prong of the test for ripeness. *Edison Elec. Institute v. EPA*, 996 F.2d 326, 333-34 (D.C. Cir. 1993); *see also CropLife Am. v. EPA*, 329 F.3d 876, 884 (D.C. Cir. 2003) (press release announcing that EPA would not consider third party human studies in regulatory decision-making was a statement of a

blanket agency policy that presented a purely legal question, ripe for review); *IBEW v. ICC*, 862 F.2d 330, 335 (D.C. Cir. 1988) (a matter is fit for review when agency's decision is "crystallized"); *Nat'l Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 695 (D.C. Cir. 1971) (an issue is fit for judicial resolution where there is no need to identify or refine the facts). The "hardship" prong of the ripeness test requires a court to avoid interfering with an agency's decision unless and until the decision involves "effects felt in a concrete way by the challenging party." *Nat'l Automatic Laundry*, 443 F.2d at 696.

The issue raised by Teva—whether the FDA's interpretation of subsection (bb)(CC) of the MMA is arbitrary and capricious under the APA—is purely a legal question fit for judicial review. It is a challenge to the FDA's interpretation of the statute on its face and not as applied to a particular set of facts. There is no need for further factual development as there is no material fact missing from the record that could alter the FDA's interpretation of the MMA.

Further, the decision affects Teva in a concrete way. To explain how it is affected by the right to exclusive marketing and the loss of that right, Teva submitted the declaration of David Marshall, Teva's Vice President of New Products Portfolio Strategy. Mr. Marshall explains that when a generic manufacturer such as Teva files a paragraph IV certification, it takes on the risk of costly and protracted patent litigation. Marshall Decl. ¶ 10. However, by being the first to take on such risk, Teva

became eligible for the 180-day exclusive marketing period. *Id.* ¶ 11. The exclusivity period provides a strong incentive because it provides a permanent advantage—"that officially sanctioned 'head start' permits first entrants to secure distribution channels and access to customers; enter into long-term sales agreements; increase sales across all of its product lines; and retain greater market share in the long-run." *Id.* Under the FDA's interpretation of the MMA as set forth in the Acrabose and Cosopt Decisions, Teva already has lost its right to the 180-day exclusive marketing period; Teva will sell 50-60% fewer losartan tablets during its first year in the market and will experience a loss of hundreds of millions of dollars in net revenue. *Id.* ¶ 16.

Teva's current day-to-day operations are concretely affected by the FDA's interpretation of forfeiture under the MMA. Teva must obtain materials to begin manufacturing generic losartan products in the immediate future, and it must obtain more materials if it is preparing for exclusive marketing than if it is preparing for non-exclusive marketing. *Id.* ¶ 22. If it enjoyed an exclusive product launch, Teva would need to place an order immediately-for delivery no later than August 2009—for the manufacture of the active pharmaceutical ingredient used to make losartan products as well as non-active ingredients and packaging materials. *Id.* ¶ 22-23. Also, Teva would need to dedicate plant capacity and human resources earlier for an exclusive

product launch as opposed to a non-exclusive launch. *Id.* ¶ 24.[9]

The FDA argues that this case is not ripe for review, relying on *Pfizer Inc. v. Shalala*, 182 F.3d 975, 980 (D.C. Cir. 1999). In that case, Pfizer sought to prevent the FDA from approving the ANDA of a competitor, Mylan. Pfizer claimed that its drug product had a unique release mechanism and that the FDA could not approve an ANDA without the same release mechanism because ANDAs are required by statute to have the same "dosage form" as the name brand drug. *See* 21 U.S.C. § 355(j)(2)(A)(i)-(iii). Prior to filing suit, Pfizer had filed a citizen petition. The FDA had denied the petition, finding that another release mechanism could provide the same dosage form. 182 F.3d at 978. Pfizer filed suit in district court, and the court granted summary judgment to the FDA. *Id.* Pfizer then appealed, and the D.C. Circuit held that Pfizer did not present a ripe claim. While the FDA had "refused to affirm the negative proposition that no other extended release mechanism could ever be deemed under the statute to

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[9] Mr. Marshall further explains, "Commercial uncertainty will impose an array of irreparable harms on Teva." Marshall Decl. ¶ 25. If Teva manufactures losartan products assuming that it does not have exclusivity and later it is awarded exclusivity, it will not have manufactured sufficient quantity of products to meet the market demand, resulting in reduced sales and loss of customer good will. *Id.* ¶ 26. If Teva manufactures generic losartan products assuming that it has exclusivity and then in April 2010 the FDA decides that it is not entitled to such exclusivity, Teva will have wasted resources manufacturing tons of tablets it cannot and may never sell, forcing Teva to dispose of excess product or liquidate it at a loss. *Id.* ¶ 27.

constitute the same dosage form as Pfizer's," the FDA had not yet applied this finding to any particular set of facts. *Id.* at 979. The court held that Pfizer's challenge raised an abstract disagreement over agency policy and was not sufficiently crystallized to constitute an actual case or controversy. *Id.* at 979-80. The FDA's reliance on Pfizer stems from its mischaracterization of Teva's claim. Unlike Pfizer, Teva does not ask the Court to preclude the FDA from approving a competitor's ANDA. Moreover, Pfizer is distinguishable because there the FDA had not yet applied its policy to a particular set of facts. Here, Teva challenges the FDA's interpretation of the MMA on purely legal grounds.

The FDA also relies on *Biovail Corp. v. FDA,* 448 F. Supp. 2d 154 (D.D.C. 2006). There, Biovail sought to require the FDA to rule on its citizen petition before approving any competing ANDA. Biovail alleged in its citizen petition that a competitor's proposed generic drug posed an unreasonable risk of seizures because it was not bioequivalent to the name brand drug. 448 F. Supp. 2d at 161. The court found that the FDA was not required to rule on the citizen petition by any particular date and that the court would not assume that the FDA would approve an unsafe drug if it did not immediately rule on the citizen petition. *Id.* at 162. In contrast, Teva is not asking the FDA to rule on the issue presented by a particular date; the FDA *already* has interpreted subsection (bb)(CC) of the MMA. To resolve this issue, the Court is not required to presume that the FDA will take any particular action in the future.

Teva's challenge to the FDA's statutory interpretation is ripe for review.

D. Standing

The FDA further suggests that Teva's suit should be dismissed for lack of standing. Lack of standing is a defect in subject matter jurisdiction. See *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987). To have Article III standing, a plaintiff must establish: "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). "This triad of injury in fact, causation, and redressability constitutes the core of Article III's case-or-controversy requirement, and the party invoking federal jurisdiction bears the burden of establishing its existence." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103-04 (1998). A court may "intervene in the administration of the laws only when, and to the extent that, a specific 'final agency action' has an actual or immediately threatened effect." *Lujan v. National Wildlife Federation*, 497 U.S. 871, 894 (1990).

The FDA contends that Teva lacks standing, in that it can show no injury because the FDA has not made a decision regarding Teva's ANDAs. Yet as described above, Teva has been injured by the FDA's

statutory interpretation. The FDA's interpretation imminently will cause Teva to lose its right to exclusive marketing, and Teva already has altered its operations due to this imminent loss. Teva's current operations are affected because it has not ordered the additional materials and dedicated the plant capacity and human resources it would need if it were planning to market its generic losartan products in an exclusive market. Marshall Decl. ¶¶ 22-24. The loss of the 180-day exclusive marketing period imminently will cause Teva to lose the ability to: secure distribution channels and access customers, enter into long-term sales agreements, increase sales across all of its product lines, and retain greater market share in the long-run. *Id.* ¶ 11. Also, the loss of exclusivity imminently will cause Teva to sell fewer losartan tablets during its first year in the market, resulting in a loss of hundreds of millions of dollars in net revenue. *Id.* ¶ 16. Teva has demonstrated standing.

E. APA Challenge to the FDA's Interpretation of the MMA

Teva challenges the FDA's interpretation of the MMA forfeiture provision set forth at 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC). The APA requires a reviewing court to set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001). In making this inquiry, the reviewing court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a

clear error of judgment." *Marsh v. Oregon Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotation marks omitted). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986). An agency action may be arbitrary or capricious if:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). "[T]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." Id. Rather, the agency action under review is "entitled to a presumption of regularity." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), abrogated on other grounds by *Califano v. Sanders*, 430 U.S. 99 (1977).

When reviewing an agency's interpretation of a statute, a court must undertake a two-step analysis as set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). First, a court must determine whether "Congress has directly spoken to

the precise question at issue" and if so the court must "give effect to the unambiguously expressed intent of Congress." 467 U.S. at 842-43. To decide whether Congress has addressed the precise question at issue, a court must analyze the text, purpose, and structure of the statute. *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 124 (D.C. Cir. 2006).

If the statute is silent or ambiguous on the question, the court must proceed to the second step of the Chevron analysis and determine whether the agency's interpretation is based on a permissible construction of the statute. *Chevron*, 467 U.S. at 843. When an agency's interpretation of a statute is challenged at step two, its "interpretation need not be the best or most natural one by grammatical or other standards.... Rather [it] need be only reasonable to warrant deference." *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991). "The court need not conclude that the agency's construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Chevron*, 467 U.S. at 844 n.11. If the agency's statutory construction is permissible, then the court must defer to the agency's interpretation. *Id.*

At *Chevron* step one, this Court must give effect to the clear intent of Congress as reflected in the statute because subsection (bb)(CC) is not ambiguous on its face. Section 355(j)(5)(D)(i)(I) provides that an ANDA filer will forfeit exclusivity if it fails to market the drug by the later of two dates, and under subsection

(bb)(CC), one of those dates is 75 days after "[t]he patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b) [the Innovator]." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

Teva asserts that the statute is ambiguous if read as a whole. First, Teva argues that the MMA governs only the effect of the withdrawal of a patent by an Innovator, but that it does not address the circumstances in which a patent may be delisted. Teva is correct that the statute does not address when an Innovator may withdraw a patent, but what is important is that the statute does not limit the Innovator's right to withdraw patent information. The Court cannot take on the role of the legislature by creating such limitations when they were omitted by Congress.[10]

Second, Teva argues that subsection (bb)(CC) should only apply when a court has ordered the Innovator to withdraw the patent pursuant to a counterclaim suit filed by an ANDA applicant. The MMA includes a "counterclaim provision" that

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[10] Further, it is not that the FDA made an incorrect judgment about whether the '075 patent should be listed or delisted. The FDA does not adjudge the propriety of patent listings. It is not required to determine the correctness of listings in the Orange Book because it lacks expertise in patent law. *Apotex v. Thompson*, 347 F.3d 1335, 1349-50 (Fed. Cir. 2003). "When it comes to the veracity of patent information supplied by NDA holders, FDA operates in a purely ministerial role, relying on the NDA holders to provide the Agency with accurate patent information." *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008).

permits an ANDA applicant sued for infringement to file a counterclaim to force an Innovator to withdraw patent information. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I). Teva claims that subsection (bb)(CC) is linked to the counterclaim provision and that (bb)(CC) only applies when a court has ordered an Innovator to withdraw patent information pursuant to a counterclaim. The problem with this interpretation is that the MMA contains no language linking the forfeiture provision and the counterclaim provision as Teva would prefer. The provisions simply do not refer to one another.

Moreover, even if subsection (bb)(CC) were construed in the context of the whole statute to be ambiguous, the Court would be required to defer to the FDA's interpretation under Chevron step two. It is not arbitrary or capricious for the FDA to interpret (bb)(CC) as broadly applying whenever an Innovator withdraws patent information because the statute provides no limitations on withdrawal of patent information and subsection (bb)(CC) makes no reference to the counterclaim provision.[11] The FDA's interpretation of the statute is reasonable.

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[11] Teva also argues that the FDA's interpretation of the MMA forfeiture provision permits a name brand manufacturer to manipulate the market by causing a first filing ANDA applicant to forfeit its right to exclusivity. This presumes that Merck was motivated to withdraw the '075 patent based solely on market concerns, when there is no evidence in the record regarding why Merck withdrew the patent. It could be that the patent was erroneously listed, Merck's interest in it lapsed, or Merck was required to withdraw the patent based on new FDA regulations. *See* Opp'n to Mot. for Prelim. Inj. filed by proposed intervenor Apotex, Inc. ("Apotex's Opp'n") [Dkt. # 11-6] at 19. The Court

Teva further argues that *Ranbaxy Laboratories Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006), applies. In *Ranbaxy*, the FDA had determined that an ANDA applicant's eligibility for the 180-day exclusive marketing period would be lost if the Innovator withdrew its patent on which the exclusivity was based and did not sue the ANDA applicant for infringement. The FDA also found that the ANDA applicant would not lose the right to exclusivity if the Innovator had sued the ANDA applicant. Ranbaxy and Teva brought suit against the FDA, arguing that the FDA could not condition eligibility for the exclusive marketing period on whether or not the Innovator had filed suit. The Circuit agreed: "[T]he FDA's requirement that a generic manufacturer's patent challenge give rise to litigation as a condition of retaining exclusivity when a patent is delisted is inconsistent with the Act, which provides that the first generic manufacturer to file an approved application is entitled to exclusivity when it either begins commercially to market its generic drug or is successful in patent litigation." *Id.* at 121.

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permits the filing of this brief on an amicus basis. *See infra*, section III.F. of this Opinion. In 2003, the FDA promulgated 21 C.F.R. § 314.53(b) which established new requirements regarding polymorph patents and the circumstances under which such patents can be said to claim a drug. The '075 patent is a polymorph patent. Teva's Mot. for Prelim. Inj. [Dkt. # 5] at 27 (the '075 patent is titled "Polymorphs of losartan and the process for the preparation of form II of losartan"). Also, Teva itself is partly responsible for the forfeiture. Teva's right to exclusivity was based only on the '075 patent because Teva filed a paragraph IV certification as to only that patent. If Teva had challenged the '069 or '197 patents, the withdrawal of the '075 patent would not have effectuated a forfeiture.

Teva reads *Ranbaxy* broadly, construing the case as overturning the FDA's interpretation of the statute because it undermined the Hatch-Waxman incentive structure. Teva reasons that this Court similarly should overturn the FDA's rule of decision set forth in the Acrabose and Cosopt Decisions for the same reason-because the FDA's interpretation of MMA subsection (bb)(CC) as applying "whenever" an NDA holder withdraws its patent also undermines the Hatch-Waxman incentive structure.

Ranbaxy was decided under the Hatch-Waxman Amendments as they existed prior to the enactment of the MMA. The Hatch-Waxman Amendments were intended both to encourage innovative new drugs and to permit the marketing of lower cost generic drugs quickly. *Tri-Bio Labs.*, 836 F.2d at 139. However, prior to the MMA, there was no provision for forfeiture of the 180-day exclusivity period. The MMA now provides that the first generic manufacturer is entitled to exclusivity if it has not forfeited that exclusivity. *See* 21 U.S.C. § 355(j)(5)(D). Thus, Congress modified the incentive structure. When enacting the MMA, Congress sought to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." *Hi-Tech*, 587 F. Supp. 2d at 4 (quoting 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (Statement of Sen. Schumer)). "Because the balance struck between these competing goals is quintessentially a matter for legislati[illegible] judgment, the court must attend closely to the terms in which Congress expressed that judgment." *Teva Pharm. Indus., Ltd. v. Crawford,*

410 F.3d 51, 54 (D.C. Cir. 2005). The FDA's interpretation of the MMA is a reasonable interpretation of the balance Congress struck between these competing goals.

F. Motion to Intervene As a Defendant

Apotex, Inc. ("Apotex") filed a motion to intervene as a defendant. *See* Dkt. # 11. Apotex filed ANDAs seeking FDA approval to market its own generic versions of losartan and losartan HCTZ products. Apotex hopes and expects that it will receive approval in time to begin marketing its products in April 2010. If Teva obtains the 180-day exclusive marketing right that it seeks in this suit, Apotex will have to sit on the sidelines for six months while Teva enjoys exclusive marketing.

An applicant may intervene as of right when the applicant (1) makes a timely motion; (2) has an interest relating to the property or transaction which is the subject of the action; (3) is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest; and (4) where the applicant's interests are not adequately represented by the existing parties. Fed. R. Civ. P. 24(a)(2); *see also Sierra Club v. Van Antwerp*, 523 F.Supp.2d 5, 6 (D.D.C. 2007). Article III standing is required for intervention under Rule 24(a)(2). *S. Christian Leadership Conference v. Kelley*, 747 F.2d 777, 779 (D.C. Cir. 1984). To demonstrate standing, a party must establish: "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly

traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth*, 528 U.S. at 180-81, 120 S.Ct. 693 (citing *Lujan*, 504 U.S. at 560-61).

Apotex asserts that its ANDAs are under review by the FDA and it expects to receive final approval to begin marketing on April 6, 2010. Apotex's expectation of final approval depends on the FDA's completion of scientific review of Apotex's ANDAs and finding no deficiencies in the ANDAs. The interest that Apotex alleges in this suit-its desire to market generic losartan in the future-presumes final approval of its ANDAs and is speculative.[12] Thus, Apotex's motion to intervene as of right will be denied.

A court may grant permissive intervention where the applicant: (1) makes a timely motion; (2) has a claim or defense; and (3) that claim or defense shares with the main action a common question of law or fact. Fed. R. Civ. P. 24(b). The requirements for

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[12] The Hatch-Waxman Amendments provide that the FDA may grant a tentative approval notifying an applicant that the ANDA meets scientific standards but cannot receive final approval until some patent barrier or other regulatory barrier (such as the exclusivity period) is overcome. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); *id.* § 355(j)(2)(a); 21 C.F.R. § 314.105(d). Final approval may be granted when an applicant has met the scientific standards for approval and the patent and regulatory barriers no longer apply. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); *id.* § 355(j)(2)(a); 21 C.F.R. § 314.105(d). The FDA has granted tentative approval to Teva's ANDAs but not to those submitted by Apotex.

permissive intervention are construed liberally in favor of intervention in special cases. *Equal Employment Opportunity Comm'n v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1046 (D.C. Cir. 1998). The decision whether to grant permissive intervention is discretionary. *In re Vitamins Antitrust Class Actions*, 215 F.3d 26, 32 (D.C. Cir. 2000).[13] Apotex's interest in this suit is a speculative business interest, i.e., a desire to enter the generic losartan market earlier rather than later. Apotex presumes that the FDA will approve its ANDAs at some point. Under these circumstances, Apotex's interest does not warrant intervention, and the Court will deny Apotex's request to intervene. However, the Court will permit Apotex to file, as amicus curiae, its opposition to preliminary injunction, which the Court has considered. See *Firestone Tire & Rubber Co. v. PBGC*, 695 F. Supp. 43, 44 (D.D.C. 1988) (the decision to appoint an amicus rests within the broad discretion of the district court).

IV. CONCLUSION

For the reasons stated above, the FDA's motion to dismiss [Dkt. # 9] will be denied. Teva's motion for preliminary injunction [Dkt. # 5] is consolidated with trial on the merits pursuant to Federal Rule of Civil Procedure 65(a)(2), and judgment will be entered in favor of the FDA. Further, the motion to intervene as a defendant filed by Apotex [Dkt. # 11] will be denied,

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[13] There is uncertainty under D.C. Circuit law whether standing is required for permissive intervention. *In re Vitamins Antitrust Class Actions*, 215 F.3d at 31-32.

but the Court will permit Apotex to file, as amicus curiae, the opposition to preliminary injunction set forth as Exhibit 5 to Apotex's motion to intervene [Dkt. # 11-6]. A memorializing order accompanies this Memorandum Opinion.

Date: July 31, 2009

Rosemary Collyer

United States District Judge

APPENDIX F

STATUTORY PROVISIONS

21 U.S.C. § 355(j)(2)(A)(vii)

(j) Abbreviated new drug applications

* * *

(2)(A) An abbreviated application for a new drug shall contain –

* * *

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section –

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]

21 U.S.C. § 355(j)(5)(B)(i), (iv)

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

> (i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

* * *

> (iv) 180-day exclusivity period
>
> > (I) Effectiveness of application Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.
> >
> > (II) Definitions
> >
> > In this paragraph:
> >
> > > (aa) 180-day exclusivity period The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period

of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

21 U.S.C. § 355(j)(5)(D)

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market The first applicant fails to market the drug by the later of –

(aa) the earlier of the date that is –

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with

respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner.

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

* * *